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Court, U.S.
FILED

No. _____

04-32 JUL 1 - 2004

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In The

Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-81 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996), both the United States Court of Appeals for the Federal Circuit and this Court endorsed an approach to claim construction in patent cases that looks first and principally to the "intrinsic evidence" (i.e., the patent's claim language, specification, and prosecution history) to determine the meaning of a disputed claim term. But despite *Markman's* effort to achieve "intrajurisdictional certainty" in this critical area of patent law, various panels of the Federal Circuit have continued to use starkly different approaches to claim construction – differences noted with increasing frequency by practitioners, by commentators,[1] and by members of the Federal Circuit itself.[2]

Under one approach, and in concert with *Markman*, some panels of the Federal Circuit rely heavily on a patent's intrinsic evidence to construe disputed claim terms. Under a competing approach, and contrary to *Markman*, some panels look first and principally to "extrinsic" dictionary definitions to determine a disputed term's "ordinary meaning," and consult the intrinsic evidence only to determine if it contains a "manifest exclusion or

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[1] *See, e.g.*, Russell B. Hill and Frank P. Cote, *Ending The Federal Circuit Crapshoot: Emphasizing Plain Meaning In Patent Claim Interpretation*, 42 IDEA: The Journal of Law and Technology 1 (2002) ("Federal Circuit ... cases manifest a palpable inter-panel tension ..."); R. Polk Wagner and Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 University of Pennsylvania Law Review 1105 (2004).

[2] *See, e.g.*, *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 898 (Fed. Cir. 2004) (concurrence by Michel, J.)

QUESTIONS PRESENTED – Continued

restriction" of that "ordinary meaning." Moreover, the selection of one approach or the other is of more than academic concern – it can be outcome determinative as was true in the claim construction dispute here.

The Federal Circuit has not, despite repeated opportunities, reconciled these conflicting precedents in an *en banc* sitting. Instead, it appears to be content with what one of its members has characterized as "absurd" results[3] and with continuing, well-documented, and very costly confusion among practitioners and district courts. Indeed, the situation has become so chaotic that, in one recent 10-month period, the Federal Circuit reversed an astounding 74% of district court decisions on claim construction.[4]

The questions presented therefore are:

1) Whether the outcome determinative "intracircuit split" within the Federal Circuit on patent claim construction should be resolved to eliminate the current unpredictable and inefficient legal environment and promote the "intrajurisdictional certainty" contemplated by *Markman*?

2) Whether disputed terms in a patent claim should be construed by looking first and principally to the "intrinsic evidence" (*i.e.*, the patent's claim language, specification,

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[3] *See Housey Pharmaceuticals, Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1356 (Fed. Cir. 2004) (dissent by Newman, J.)

[4] David J.F. Gross, et al., *You Must be Mistaken: Federal Circuit 'Corrections' of District Court Claim Constructions (2002-03)*, 766 PLI/Pat 47, 53 (2003) (error rate of 74% based on review of published claim construction decisions from approximately September 2002 through June 2003).

QUESTIONS PRESENTED – Continued

and prosecution history),[5] or by looking first and principally to extrinsic dictionary definitions to determine the term's "ordinary meaning," and then consulting the intrinsic evidence merely to determine if it contains a "manifest exclusion or restriction" of that "ordinary meaning"?[6]

3) Whether a patent claim should be broadly construed based on a dictionary-defined "ordinary meaning" to cover a device that was (a) not mentioned anywhere in the patent's specification, (b) not invented by the patent applicants, and (c) unknown in the art at the time that the patent was filed?[7]

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[5] *See, e.g., Markman*, 52 F.3d at 978-81.

[6] *See, e.g., Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002).

[7] *See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004).

PARTIES TO THE PROCEEDINGS

Petitioner

Medrad, Inc.

Respondents

Liebel-Flarsheim Company and Mallinckrodt, Inc.

DISCLOSURE STATEMENT

Petitioner Medrad, Inc. is a wholly-owed subsidiary of Schering Berlin, Inc. Schering Berlin, Inc. is a wholly-owned subsidiary of Schering Aktiengesellschaft. There is no public company that holds more than 10 percent of Schering Aktiengesellschaft's stock.

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Manual of Patent Examining Procedure § 2163 (8th ed. August 2001, revised May 2004) 24

OTHER PUBLICATIONS

Gretchen Ann Bender, *Uncertainty and Unpredictability in Patent Litigation: The Time Is Ripe for a Consistent Claim Construction Methodology*, 8 J. Intell. Prop. Law 175 (2001) 23

David J.F. Gross, et al., *You Must be Mistaken: Federal Circuit 'Corrections' of District Court Claim Constructions (2002-03)*, 766 PLI/Pat 47 (2003) ii

Ben Hattenbach, *Chickens, Eggs, and Other Impediments to Escalating Reliance on Dictionaries in Patent Claim Construction*, 85 J. Pat. & Trademark Off. Soc. 181 (2003) 23

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Anthony R. Zeuli and Rachel Clark Hughey, *Avoiding Claim Construction Errors: Determining the Ordinary and Customary Meaning Before Reading the Written Description*, The Federal Lawyer, June 2004 28

PETITION

Petitioner Medrad, Inc. (hereinafter "Medrad") respectfully requests that a writ of certiorari issue to review the April 2, 2004 judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

This petition is from the Federal Circuit's published opinion in *Liebel-Flarsheim Co. v. Medrad, Inc.*, Nos. 03-1082, 03-1165, 358 F.3d 898 (Fed. Cir. 2004), issued on February 11, 2004. (App. 1-34). That decision reversed an unpublished judgment of the United States District Court for the Southern District of Ohio, dated October 30, 2002. (App. 35-36). The Federal Circuit, after calling for a response, denied Medrad's combined petition for panel rehearing and rehearing *en banc* on April 2, 2004. (App. 131-132).

A copy of the Federal Circuit's opinion is included in the Appendix at App. 1. A copy of the district court's judgment is included at App. 35. Copies of the district court's October 18, 2001, and February 19, 2002 rulings, which formed the basis for its judgment, are included at App. 37 and App. 105, respectively. A copy of the denial of the combined petition for panel rehearing and rehearing *en banc* is included at App. 131.

I.

JURISDICTION

The district court exercised jurisdiction over this matter pursuant to 28 U.S.C. § 1338(a). The district court

entered a final judgment on October 30, 2002, which was appealed by respondents to the United States Court of Appeals for the Federal Circuit pursuant to 28 U.S.C. § 1291 and 28 U.S.C. § 1295(a)(1). The Federal Circuit rendered its decision on February 11, 2004, and Medrad timely filed its combined petition for panel rehearing and rehearing *en banc* on February 25, 2004. On March 10, 2004, the Federal Circuit called for a response to that combined petition. On April 2, 2004 the Federal Circuit denied the combined petition. Medrad timely filed this Petition for Writ of Certiorari within 90 days of that denial. This Court has jurisdiction under 28 U.S.C. § 1254(1).

II.

STATUTORY PROVISIONS INVOLVED

Article I, Section 8, Clause 8 of the Constitution:

> Congress shall have the power . . . to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their Respective Writings and Discoveries.

35 U.S.C. § 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 112 ¶¶ 1, 2:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear,

concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

III.

STATEMENT OF THE CASE

In this case, reliance on extrinsic dictionary definitions as a basis for patent claim construction passes the point of "absurdity." For the first time when applying a so-called "ordinary meaning" approach, a panel of the Federal Circuit has extended a patent claim beyond what the inventor actually invented and disclosed to a device that was admittedly unknown at the time the patent was filed. The Court embraced this result simply because the inventor did not "manifestly disclaim" this device anywhere in the patent's specification – an impossibility given that such a device was unknown at the time the patent was filed. Under this rationale, the scope of patent claims is no longer determined by what the inventor publicly disclosed as his or her actual invention, but instead depends on the broadest possible construction that a court can divine from an extrinsic dictionary long after the patent was filed.

This action was brought by the Respondent Liebel-Flarsheim Company (hereinafter "L-F"), in the United States District Court for the Southern District of Ohio in 1998, for infringement of U.S. Patent Nos. 5,456,669 ("the

'669 patent") (Pat. 1-23); 5,658,261 ("the '261 patent") (Pat. 24-46); 5,662,612 ("the '612 patent") (Pat. 47-68); and 5,928,197 ("the '197 patent") (Pat. 69-92). All four patents involve a medical device known as a power injector and the syringes used with it. Power injectors push contrast fluid from the syringe into a patient's bloodstream at a high pressure.

In the first two patents (the '669 and '261 patents), L-F only disclosed and described an injector and a syringe that used a "pressure jacket." (App. 52-55). In particular, L-F disclosed in the specifications of these patents that:

> According to the principles of the present invention, there is provided an angiographic injector having a front end loadable syringe that can be loaded into and removed from the injector pressure jacket through an opening that is provided in the front end of the pressure jacket.

'669 Patent, col. 2, line 64 to col. 3, line 1 (Pat. 13-14); '261 Patent, col. 2, lines 61-65 (Pat. 36).

Medrad's power injectors and syringes, on the other hand, do not need or use a pressure jacket. (App. 4). Medrad was, in fact, the first to invent, and the first to file a patent that explicitly disclosed, pressure jacketless injectors and syringes. (App. 39). L-F nevertheless argued that because certain of its patent claims included the words "opening" or "syringe receiving opening," rather than the words "pressure jacket," the language of the claims was broad enough to include a jacketless injector. (App. 49-50). L-F maintained that the claims should read that way even though: (1) a jacketless injector did not exist in the prior art at the time its patent was filed (App. 38, 39); (2) a jacketless injector was not disclosed anywhere in

the specifications of the '669 and '261 patents (App. 52-53, 57), each of which referenced a pressure jacket over 100 times (Pat. 1-19, 23-42); (3) the specifications of the '669 and '261 patents defined the "opening" as being "in the front end of the pressure jacket" (App. 3-4, 52-55, 59); (4) all of the claims of the original patent application required and explicitly recited a "pressure jacket" (App. 58); and (5) at one point during the prosecution of the original patent application,[8] L-F specifically added the words "pressure jacket" back into every claim after attempting to remove them to "clarify the inventive concepts claimed."

The second two patents (the '612 and '197 patents) involved a similar dispute concerning whether the term "related to" should be construed in accord with its full dictionary definition or should be construed according to how it was used in the patents' specifications. (App. 118-119).

A. By Placing Initial And Primary Reliance On The Entire Intrinsic Record When Construing The Disputed Claim Terms, The District Court Found No Infringement

Based on a review of the intrinsic evidence (the claim language, specification, and prosecution history of the patents), the district court construed the disputed claim terms "opening" and "syringe receiving opening" as used in the '669 and '261 patents to be limited to the open front

[8] The original "patent application" mentioned here is the parent application to, and has the same specification as, the '669 and '261 patents. (App. 39 n.2). Statements made or actions taken in the prosecution of this original parent application limit the coverage in the later filed '669 and '261 patents.

end of a pressure jacket. (App. 62-63). In so doing, the district court rejected the dictionary definition of "opening," e.g., "APERTURE," because it was "ambiguous with respect to the requirement of a pressure jacket." (App. 51-52). Citing *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882-83 (Fed. Cir. 2000), and *Wang Labs., Inc. v. America Online, Inc.*, 197 F.3d 1377, 1382 (Fed. Cir. 1999), the district court opined that "the asserted claims do not cover a jacketless injector, even though the asserted claims might be considered broad enough to disclose a jacketless injector when read without reference to the specification" because the "specification makes clear that the injector includes a pressure jacket." (App. 55).

The district court similarly rejected a broad dictionary definition of "related to" as used in the '612 and '197 patents based on its review of the intrinsic evidence, holding that a narrower construction of the term was "readily apparent from the language of the asserted claims themselves." (App. 120).

B. By Placing Initial And Exclusive Reliance On Extrinsic Dictionary Definitions When Construing The Disputed Claims, The Federal Circuit Rejected The District Court's Claim Construction

The Federal Circuit reversed the district court on all four patents. (App. 2). The Federal Circuit relied on an extrinsic dictionary definition to hold that "[i]n common usage, an opening is simply an aperture." (App. 13).[9]

[9] Although the Federal Circuit did not explicitly state where it found this definition of "opening," it is evident that this definition is

(Continued on following page)

Citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002), and *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002), the Federal Circuit noted that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" (App. 14) (citing *Teleflex*, 299 F.3d at 1327). Thus, although it was undisputed that a jacketless injector was unknown in the art and was not disclosed in L-F's patent specification (App. 39, 52 n.10, 56), because L-F had not manifestly disclaimed a jacketless injector, the patent claims and the term "opening" were held to cover a jacketless injector. (App. 8, 18-19, 26).

In arriving at this more expansive construction, the panel explicitly rejected several published precedents relied on by Medrad (App. 14-18), including *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed. Cir. 2001); *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed. Cir. 1999); *Biogen, Inc. v. Berlex Labs, Inc.*, 318 F.3d 1132, 1139-40 (Fed. Cir. 2003); *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882-83 (Fed. Cir. 2000); *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000); *Modine Manuf. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550-51 (Fed. Cir. 1996); and *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1301-02 (Fed. Cir. 1999), all of which provide that the language of the specification should be considered and applied in determining the meaning of the claim without

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taken from the dictionary definition cited by the district court. *Compare* App. 51 *to* App. 13.

regard to extrinsic evidence, such as a dictionary definition. (App. 14-18).

In construing the phrase "physical indicia related to" in the second dispute, the Federal Circuit took the same approach. It rejected the district court's claim construction analysis based on the intrinsic record, and instead gave the broadest possible dictionary meaning to the disputed claim terms. (App. 33).

IV.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's jurisprudence on claim construction has been in a chaotic state for several years. How else could one explain the 74% rate of reversal of district court claim construction decisions in 2002-2003? In the current circumstances, lower courts spend countless hours adjudicating patent cases only to have their decisions overturned. Litigants spend hundreds of thousands of dollars and years of effort needlessly. Patent owners and aspiring patentees alike are prevented from realizing the true value of their inventive efforts, as they are unsure about what any particular patent covers.

Although the Federal Circuit attempted to clarify the process of claim construction in 1995 with its *en banc* decision in *Markman*, 52 F.3d 967, divergent schools of thought have evolved among the members of that Court in the ensuing years. In essence, the Federal Circuit is divided between intrinsic, *Markman*-based claim construction and extrinsic, dictionary-based claim construction. Further, these disparate approaches are applied in an unpredictable manner so that inventors, patent owners,

businesses, litigants, members of the patent bar, and even the district courts, cannot possibly know how claims will be construed until after a Federal Circuit decision has been rendered. *See* Gross, *supra* footnote 4, at 113 ("A cynic may respond by suggesting that district courts should do nothing more than figure out ways to move cases to the Federal Circuit early so that the Federal Circuit can determine the 'correct' interpretation before the litigants and courts spend too much time and resources on the case.").

The state of the law governing claim construction has deteriorated so badly that not only commentators, but also members of the Federal Circuit, have noted the lack of reliable results in patent matters. Only two months ago, comments by Judge Newman, in *Housey Pharmaceuticals v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1356 (Fed. Cir. 2004), highlighted the problem: "My colleagues' approach to construction is based on confusing recent pronouncements of panels of this Court, contravening earlier statements of precedent, thus adding to the confusion."

With billions of dollars spent annually on research and development, and with hundreds of millions dollars at stake in patent infringement cases annually, this chaotic situation must end. This Court explained why in its opinion in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002): "A patent holder should know what he owns, and the public should know what he does not." Neither patent holders, nor the public, are in that position now. It is instead apparent that the "intrajurisdictional certainty" hoped for in *Markman* has not been realized, and that the Federal Circuit has been unable or unwilling to resolve the confusion in a timely fashion. It therefore is appropriate and necessary for this

Court to end the conflict and bring uniformity and predictability to claim construction in patent cases.

A. The *Markman* Decisions Were Intended To Bring Uniformity And Predictability To Patent Claim Construction

In *Markman*, the *en banc* Federal Circuit addressed two critical issues on which federal courts had divided: (1) whether patent claims should be construed by a judge or a jury; and (2) what evidence principally should be considered in construing patent claims.

On the first issue, the Federal Circuit held that claim construction is a legal issue to be decided by the court. *Markman*, 52 F.3d at 979. On the second, "[b]ecause patents are fully integrated written instruments," the Federal Circuit placed dispositive emphasis on the so-called "intrinsic evidence" in construing a claim: the claim language, specification, and prosecution history. *See id.* at 978-79 ("[c]laims must be read in view of the specification, of which they are a part."). Although a court may consult "extrinsic evidence," including dictionaries, such "evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Id.* at 981. Thus, under the *en banc* opinion in *Markman*, intrinsic evidence "is of primary significance in understanding the claims," and extrinsic evidence, such as a dictionary, is considered only when the intrinsic evidence does not provide an answer on the meaning to be given disputed claim terms. *See id.* at 978-80.

In affirming the Federal Circuit in *Markman*, this Court agreed that "the construction of a patent, including terms of art within its claims, is exclusively within the

province of the court." *Markman*, 517 U.S. at 372. By giving construction disputes to the courts and not juries, this Court expressed its desire to promote greater "intra-jurisdictional certainty" with regard to claim construction decisions. *Id.* at 391. This Court also specifically endorsed a construction approach utilizing the entire "intrinsic record," emphasizing that standard rules of construction required that a patent's terms should "be defined only in a way that comports with the instrument as a whole." *Id.* at 389.

B. In Contravention Of The *Markman* Decisions, There Now Is A Confusing And Unacceptable Split Within The Federal Circuit Concerning The Proper Approach To The Construction Of Patent Claims

Although the respective *Markman* decisions plainly were intended to bring consistency to patent claim construction, they unfortunately have not achieved their central purpose. The intervening years have not established the hoped for "intrajurisdictional certainty." *Markman*, 517 U.S. at 391. On the contrary, the Federal Circuit now employs two divergent approaches to patent claim construction: one placing primary reliance on the intrinsic record as endorsed in *Markman*; and another more recent one placing primary reliance on non-technical dictionary definitions at the expense of the intrinsic record.

The differing resolutions by the district court and Federal Circuit in this case bring this intracircuit conflict sharply into focus. Simply put, and as illustrated here, the competing approaches to patent claim construction are not reconcilable – the selection of one or the other is outcome determinative and leads to opposite results. What remains

is an unstable legal environment in which the public, the district courts, and even the Federal Circuit's own judges, can no longer determine the controlling legal rules.

Perhaps not surprisingly, the deleterious effect of these published conflicting views falls most heavily on the district courts. Those courts – on the front lines of the claim construction disputes – do not know which approach to follow, and they are at risk of reversal depending on which one they choose. The result is costly judicial inefficiency that relegates patent claim construction to the proverbial "crap shoot." Incredibly, the Federal Circuit's reversal rate for claim construction decisions recently reached an indefensible 74%. *See* Gross, *supra* footnote 4, at 53.

In this case, the Federal Circuit also has taken the utilization of dictionary definitions to an illogical extreme. Here, the Federal Circuit unilaterally defined a claim term to cover a particular embodiment that admittedly was *not* disclosed in the patent specification (App. 56) and concededly was *unknown* in the art at the time the patent was filed. (App. 39). The inventors therefore got credit for something they did not invent or intend to patent. This is problematic because the entire patent system – as established by the Constitution and The Patent Act and as affirmed by the jurisprudence of this Court and other federal courts – is designed to protect only what inventors actually discovered and expressly disclosed. *See* U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C. § 101; 35 U.S.C. § 112 ¶ 1, 2; *Markman*, 517 U.S. at 373. The Federal Circuit's opinion below is thus one of those "absurd results" identified by Judge Newman in her dissent in *Housey Pharmaceuticals*, 366 F.3d at 1356, where she outlines the flaws

inherent in placing primary reliance on dictionary definitions at the expense of the full intrinsic record.

With hundreds of millions of dollars at stake in patent infringement suits nationwide, our legal system cannot tolerate this kind of uncertainty or absurdity. As Judge Newman also succinctly stated in *Housey Pharmaceuticals*: "It is time to restore the law of claim construction to a more apt wisdom and more usable simplicity." *Id.* at 1356. The ability to assess the scope of claims using a uniform approach on a consistent basis to achieve predictable results is fundamental to the patent system and of great importance to the lower courts, the patent bar, and the commercial world. Indeed, this Court recently underscored the paramount importance of these concerns in its opinion in *Festo Corp.*, 535 U.S. at 730-31:

> The [patent] monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not.

A critical body of federal commercial law is now so confused that a district court's chances of being affirmed on appeal are less than its chances of winning a coin toss. Only this Court, in the exercise of its supervisory powers, can remedy this clear departure from the accepted and usual course of judicial appellate review. *See* Sup. Ct. R. 10(a) ("Considerations Governing Review on Certiorari").

C. The Federal Circuit's Competing Approaches To The Construction Of Patent Claims Are Outcome Determinative But Not Reconcilable

1. The Patent Claim Construction Decisions That Follow A *Markman*-Based Approach Place Initial And Primary Reliance On The Entire Intrinsic Record Before Considering Extrinsic Evidence

The Federal Circuit decisions following *Markman* make intrinsic evidence the linchpin of the construction analysis, and refuse to allow extrinsic evidence – and particularly a dictionary definition – to trump the meaning derived from the intrinsic record.

For example, in *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473 (Fed. Cir. 1998), the Federal Circuit emphasized that "the court starts the [claim construction] process" by reviewing the same sources as would a person of ordinary skill in the field of invention, "viz., the patent specification and the prosecution history." *Id.* at 1477; *see also Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1318 (Fed. Cir. 2004). The patent specification and prosecution history "have legal as well as technological content, for they show not only the framework of the invention as viewed by the inventor, but also the issues of patentability as viewed by the patent examiner." *Multiform Desiccants*, 133 F.3d at 1477.

Under this *Markman*-based approach, extrinsic evidence (like a dictionary or other independent source) may be consulted only *after* first considering the import of the patent's specification: "Courts must exercise caution lest dictionary definitions . . . be converted into technical terms of art having legal, not linguistic, significance. The

best source for understanding a technical term is the specification from which it arose . . . When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." *Id.* at 1478.

Further, consistent with the reasoning in *Markman*, a dictionary is relied on in claim construction only to the extent that "the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582, 1584 & n.6 (noting that the specification "[u]sually . . . is dispositive" in claim construction and "is the single best guide to the meaning of a disputed term"); *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 705-06 (Fed Cir. 1997) ("When construing a claim, a court should look first to the intrinsic evidence. . . . When the intrinsic evidence is unambiguous, it is improper for the court to rely on extrinsic evidence."); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("[A] common meaning, such as one expressed in a relevant dictionary, that flies in the face of the patent disclosure is undeserving of fealty."); *Toro Co.*, 199 F.3d at 1299-1302 (rejecting dictionary definitions and emphasizing that claim terms must be construed "in the context in which they were used by the inventor, considered by the examiner, and understood in the field of the invention"); *Vanderlande Indus.*, 366 F.3d at 1322 (rejecting dictionary definition as being "entirely eclipsed by the . . . patent's written description").

In fact, in keeping with the *Markman*-based approach, where a particular claim term has no special meaning in the relevant industry (independent of the specification), "general-usage dictionaries are rendered irrelevant with

respect to that term." *Vanderlande Indus.*, 366 F.3d at 1321. Thus, "[i]n those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." *Vitronics*, 90 F.3d at 1583.

2. The Patent Claim Construction Decisions That Follow The "Ordinary Meaning" Approach Place Initial And Primary Reliance On Extrinsic Evidence At The Expense Of The Intrinsic Record

Rather than placing primary reliance on the intrinsic record, a divergent line of Federal Circuit decisions places primary and dispositive emphasis on the "ordinary meaning" of claim terms as ascertained by reference to extrinsic dictionary definitions. *See, e.g.*, *Liebel-Flarsheim*, 358 F.3d at 905 (App. 11-13); *Teleflex, Inc.*, 299 F.3d at 1327; *Texas Digital*, 308 F.3d at 1202-04.

These cases hold that court-selected dictionary definitions disclose a claim term's "ordinary meaning," and that there is a "heavy presumption" that such a dictionary-defined "ordinary meaning" is correct. Under this "ordinary meaning" approach, the patent's specification is relegated to the back seat, and is relevant only insofar as it demonstrates "a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *See Liebel-Flarsheim*, 358 F.3d at 906 (*citing Teleflex*, 299 F.3d at 1327) (App. 13-15).

3. The *Markman*-Based And The "Ordinary Meaning" Approaches To Patent Claim Construction Are Irreconcilable And Lead To Inconsistent Results

The *Markman*-based approach and the "ordinary meaning" approach – both reflected in the Federal Circuit's published case law – conflict with each other in three fundamental and irreconcilable ways.

First and foremost, the "ordinary meaning" approach gives dispositive weight to court-selected, extrinsic dictionary definitions in the claim construction analysis. Non-technical dictionaries are viewed as the "most meaningful sources of information to aid judges in better understanding both the technology and terminology used by those skilled in the art to describe the technology." *Texas Digital*, 308 F.3d at 1203. In contrast, cases that use the *Markman*-based analysis focus on the specification and relegate dictionary definitions to the proverbial back seat. *See, e.g.*, *Vitronics Corp.*, 90 F.3d at 1582 (the specification "[u]sually . . . is dispositive" in claim construction and "is the single best guide to the meaning of a disputed term"); *Vanderlande Indus.*, 366 F.3d at 1322 (ordinary dictionary definition of "glide surface" is "entirely eclipsed" by the patent's written description).

Second, and equally important, under the "ordinary meaning" approach, the meaning of the claim term is determined *first* by reference to a non-technical dictionary. *See, e.g., Texas Digital*, 308 F.3d at 1205. The remaining "intrinsic evidence," such as the specification and written description, is considered only if the court-selected dictionary meaning fails to resolve the issue. *Id.* at 1204; *see, e.g., Housey Pharmaceuticals*, 366 F.3d at 1352; *Inverness Medical Switzerland GmbH v. Warner Lambert Co.*, 309

F.3d 1373, 1382 (Fed. Cir. 2002). Under *Markman*, in contrast, *all* of the intrinsic evidence is considered *first*, and extrinsic evidence is considered only if the claim term's meaning remains ambiguous in light of the intrinsic evidence. *See Multiform Desiccants*, 133 F.3d at 1477-78.

Third, and just as fundamental, by placing paramount reliance on court-selected dictionary definitions, the "ordinary meaning" approach disregards what the inventors actually invented, as disclosed by their own patent application, and what the Patent Office examined in granting the patent. As the Federal Circuit stated here: "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim*, 358 F.3d at 906 (App. 13-15).

However, as Judge Newman has explained, this express disregard for the written description also conflicts with *Markman*: "Precedent is exactly contrary: a claim is 'inimical' to any broader construction than the invention set forth in the specification, and reliance on dictionaries, even technical dictionaries, without due consideration of the context of the invention may lead to 'absurd results.'" *Housey Pharmaceuticals*, 366 F.3d at 1356.

Judge Michel, in his very recent concurrence in *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 896-98 (Fed. Cir. 2004), also noted the dispositive differences between the "ordinary meaning" and the *Markman*-based approaches and captured the essence of the problem the conflict engenders:

> I am concerned then that the use of these "shorthand" expressions about ordinary meaning obscures the correct analysis, tempting panels to look for an "ordinary meaning" divorced from the proper perspective – the artisan's – and the preferred, proper sources of interpretation – the disclosure, technical dictionaries, prior art patents, and expert testimony. The ultimate result of this trend is claim constructions providing the broadest possible scope to claim terms, absent express limiting language in the claim, specification or prosecution history, but regardless of what the inventors actually invented.

Id. at 898.

These dichotomies, aptly described by the Federal Circuit's own judges and highlighted here, are by no means trivial or just a matter of semantics. The construction approach a court selects can be dispositive of claim construction. Depending on the composition of panels and the approach the judges favor, results can vary as well. *See* R. Polk Wagner and Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 Univ. of Pennsylvania Law Review 1105, 1112 (2004).

4. This Case Starkly Illustrates The Dispositive Effect Of The Choice Of One Claim Construction Approach Or The Other

This case provides an unusually stark illustration of how the selection of one claim construction approach or the other can control the outcome of a claim construction dispute. There is no question here, for example, that L-F's

patented medical device requires a pressure jacket and that the specification and prosecution history reveal that the syringe receiving "opening" is in the front of the pressure jacket. Only by ignoring the specification and prosecution history, in favor of a much broader and non-technical dictionary definition, can L-F's patent claim be read to cover Medrad's jacketless injector. The same goes for "physical indicia related to." When that phrase is considered in light of what L-F actually invented – as revealed from the specifications and prosecution history – it has no colorable relevance to Medrad's device.

The irreconcilable nature of these conflicting approaches is further illustrated by *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1346-51 (Fed. Cir. 2004) – a case published just eight days before this one with remarkably similar facts but a totally different outcome.[10] In *Microsoft*, "transmitting" was limited to transmission over a telephone line by the district court just like "opening" was limited to the opening at the front of the pressure jacket by the district court in the present case. In *Microsoft*, transmission over a telephone line was mentioned two dozen times in the specification, the stated "invention" included telephone lines, and the specification did not mention transmission that was not over a telephone line. Similarly, in this case, pressure jacket is mentioned over 135 times in the specification, the "invention" included a pressure jacket, and the specification did not mention an

[10] Medrad understands that Multi-Tech Systems is also filing a Petition for Writ of Certiorari from this decision by the Federal Circuit during the week of June 28, 2004. Presumably, its petition will also address the Federal Circuit's divergent claim construction approaches.

injector that did not include a pressure jacket. (App. 52-55, 57; Pat. 1-19, 23-42).

In *Microsoft*, however, unlike the present case, the Federal Circuit affirmed summary judgment of non-infringement based on the district court's narrow construction of the claim term at issue ("transmitting"). The Federal Circuit did not reference the "ordinary meaning" and "manifest exclusion" analysis it used in this case, but rather relied on the *Markman*-based approach wherein "the claims must be interpreted in light of the specification." *Microsoft*, 357 F.3d at 1347.

Had the *Markman*-based approach employed in *Microsoft* been applied in the present case, the district court's claim construction would have been affirmed. And, had the "ordinary meaning" approach applied by the Federal Circuit in this case been applied in *Microsoft*, the outcome would have been different there as well.

5. The Intolerable Uncertainty Created By The Federal Circuit's Conflicting And Competing Patent Claim Construction Approaches Should Be Rectified Now By This Court

a. The Federal Circuit's Competing Claim Construction Opinions Provide Inadequate Guidance And Exacerbate The Conflict

As Judge Dyk acknowledged when examining this intracircuit conflict three years ago: "our decisions provide inadequate guidance as to when it is appropriate to look to the specification. . . . Until we provide better guidance, I fear that the lower courts and litigants will remain

confused." *SciMed Life Sys., Inc.*, 242 F.3d at 1347 (concurring opinion); *see also VLT Corp. v. Lambda Elect., Inc.*, 238 F. Supp. 2d 347, 350 (D. Mass. 2003) (describing the Federal Circuit's precedents as "a bit schizophrenic on the relationship between the claim language and the specification of a patent"); *BorgWarner, Inc. v. New Venture Gear, Inc.*, 237 F. Supp. 2d 919, 928 (N.D. Ill. 2002) (discussing the "tension" in the Federal Circuit's precedent concerning the role of the specification in claim construction).

Despite Judge Dyk's plea, the confusion has persisted and gotten worse, not better. For example, just three months ago, Judge Dyk dissented from a claim construction decision because "[t]he majority decision effectively limits the claims to the preferred embodiment, contrary to our recent decision in *Liebel-Flarsheim*, 358 F.3d 898, and numerous other decisions of this Court." *Phillips v. AWH Corp.*, 363 F.3d 1207, 1216 (Fed. Cir. 2004). Just two months ago, by comparison, Judge Newman dissented from a claim construction decision that employed the "ordinary meaning analysis" because: "My colleagues' approach to construction is based on confusing recent pronouncements of panels of this Court, contravening earlier statements of precedent, thus adding to the confusion." *Housey Pharmaceuticals*, 366 F.3d at 1356.

Apart from the Federal Circuit's own judges, the persistence of this intracircuit inconsistency, as well as the fundamental problems it engenders for claim construction, have been highlighted by commentators as well:

> The Federal Circuit's lack of a consistent claim construction methodology becomes most apparent when trying to determine when extrinsic evidence, particularly dictionaries and treatises,

> may be considered. . . . In many cases, the Federal Circuit determines the plain and ordinary meaning of the claim terms by relying on extrinsic evidence, such as dictionaries and even expert testimony. In other cases, the court ignores extrinsic evidence about the ordinary meaning of claim terms. In sum, not only are the claim construction canons ideologically flawed (and impossible to apply), but also the Federal Circuit does not approach claim construction consistently. Under the circumstances, uncertainty and unpredictability in patent cases will undoubtedly continue.

Gretchen Ann Bender, *Uncertainty and Unpredictability in Patent Litigation: The Time Is Ripe for a Consistent Claim Construction Methodology*, 8 J. Intell. Prop. Law 175, 217 (2001).[11]

b. The Persistent Conflict In Claim Construction Approaches Erodes The Role Of The PTO

This persistent conflict in approaches adversely impacts the role of the Patent and Trademark Office

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[11] *See also* Ben Hattenbach, *Chickens, Eggs, and Other Impediments to Escalating Reliance on Dictionaries in Patent Claim Construction*, 85 J. Pat. & Trademark Off. Soc. 181, 182, 190 (2003) (noting that recent Federal Circuit cases on use of dictionary definitions "deviated from established principles of construction" and that earlier cases "struck a sensible balance between dictionaries and specifications"); Russell B. Hill and Frank P. Cote, *Ending the Federal Circuit Crapshoot: Emphasizing Plain Meaning in Patent Claim Interpretation*, 42 IDEA: The Journal of Law and Technology 1, 1 (2002) ("The tension between these camps [regarding the role of plain meaning in patent claim interpretation], which is driven by competing canons of claim construction, results in uncertainty for litigants and wasted judicial resources.").

("PTO") as well. By giving judge-selected dictionary definitions priority over the intrinsic specification, the Federal Circuit's "ordinary meaning" approach invites courts to construe claim terms more broadly than the limits directed in the patent's specification. But the PTO, as part of its threshold oversight function, is directed to reject any claims that it finds are unsupported by the specification. *See* Manual of Patent Examining Procedure § 2163 (8th ed. August 2001, revised May 2004). Thus, from the Federal Circuit's "ordinary meaning" perspective, the specification has little, if any, significance whatsoever, while from a regulatory perspective it is supposed to be dispositive. This anomalous result further compromises the efficacy of the PTO.[12]

c. The Persistent Conflict In Claim Construction Approaches Erodes The Important Notice Function Of The Patent System

The Federal Circuit's persistent conflict in claim construction approaches erodes the important notice

[12] This anomaly is reason alone to reject the "ordinary meaning" approach. *See, e.g., Festo Corp.*, 535 U.S. at 738 (adopting legal rule that is "respectful of the real practice before the PTO"); *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 n.6 (1997) (declining to adopt legal rule where "the PTO may have relied upon a [different] rule . . . when deciding whether to [issue a patent] in the first place"); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 18-19 (1966) (decrying "a notorious difference between the standards applied by the Patent Office and by the courts," and adopting legal rule that would "bring about a closer concurrence between administrative and judicial precedent"). The specification, which "show[s] not only the framework of the invention as viewed by the inventor, but also the issues of patentability as viewed by the patent examiner," *Multiform Desiccants*, 133 F.3d at 1477, provides much surer guidance to the meaning of a disputed claim term than an extrinsic dictionary definition.

function supplied by the public record or "intrinsic evidence." *See, e.g., Markman*, 517 U.S. at 390 ("The limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public.") (citation omitted). As the Federal Circuit has stated, "competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention." *Vitronics*, 90 F.3d at 1583.[13]

Nevertheless, the divergent claim construction approaches directly undermine this public notice function in two critical ways: first, by making it impossible for district courts, competitors, and the public to ascertain how a claim will be construed; and second, by diminishing the extent to which anyone can rely on the public record to determine what actually has been claimed. For these reasons, a competitor never really can be sure which approach will be used and what role the public record will subsequently play in claim construction.

In such an environment, there is little left of the public notice function that is at the heart of the patent system. While the intrinsic specification is part of "the public record of the patentee's claim" examined by the

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[13] *See also Bates v. Coe*, 98 U.S. 31, 39 (1878) ("Accurate description of the invention is required by the law, for several important purposes: 1. That the government may know what is granted, and what will become public property when the term of the monopoly expires. 2. That licensed persons desiring to practise [sic] the invention may know during the term how to make, construct, and use the invention. 3. That other inventors may know what part of the field of invention is unoccupied.").

PTO, *Vitronics*, 90 F.3d at 1583, judge-selected dictionary definitions are not. Allowing an inventor to broaden a claim's scope by a judge's hindsight reliance on a dictionary definition thus renders "meaningless" the public's right to rely on the intrinsic record. *Id.*

d. The Persistent Conflict In Claim Construction Approaches Erodes The Patent System Itself

In the end, the Federal Circuit's persistent conflict in claim construction approaches erodes the patent system itself. The U.S. Constitution and the Patent Act set up the patent system to secure to "Inventors the exclusive right to their . . . Discoveries." U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C. § 101. The Patent Act further requires that the inventor provide a "written description of the invention" in "full, clear, concise, and exact terms." 35 U.S.C. § 112, ¶ 1. Thus, as this Court has noted:

> It has long been understood that a patent must describe the exact scope of an invention and its manufacture to "secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them."

Markman, 517 U.S. at 373 (citations omitted) (additions and quote as in original).

As is starkly illustrated in this case, the choice of claim construction approach can greatly impact the scope and coverage of the claims. The persistent conflict in approaches thus erodes the patent system by making it impossible to "apprise the public of what is still open to them." *See id.*

Moreover, the "ordinary meaning" approach employed by the Federal Circuit also erodes the system by disregarding what the inventor actually invented and disclosed. As described by the *en banc* Federal Circuit, the patent system, in essence, works a "deal" between the inventor and the government:

> The inventor is required to make full disclosure of his invention to the Patent and Trademark Office (PTO) and to the public in his patent specification, which he is otherwise not obligated to do. In return, the law allows the government to confer a property right to exclude anybody else from making, using, or selling the invention covered by the claims for seventeen years, which it is not obligated to do.

Markman, 52 F.3d at 985. Yet, by disregarding what actually was disclosed by the inventor, the continued reliance on the "ordinary meaning" approach directly undermines the deal that is at the heart of the Patent System.

e. The Time Is Ripe For Laying The Conflict In Claim Construction Approaches To Rest

Given the uncertainty and absurdity inevitably engendered by the "ordinary meaning" approach, the *Markman*-based reliance on the entire intrinsic record should be preferred and restored to favor. But whatever approach is deemed most desirable, the present conflict in the legal standards applicable to patent claim construction should be immediately laid to rest. The district courts, affected competitors, litigants, the PTO, and ultimately the patent system, all are casualties of this divergence.

Uniformity and predictability from judicial decision making should be paramount goals in this context given the hundreds of millions of dollars at stake on patent infringement issues. Yet, the Federal Circuit's own decisions, when combined with its reversal rate, reveal how badly these goals are being compromised. In short:

> Trial judges are frustrated. Lawyers grapple with the uncertainty of the process. Clients loathe the expense.

Anthony R. Zeuli and Rachel Clark Hughey, *Avoiding Claim Construction Errors: Determining the Ordinary and Customary Meaning Before Reading the Written Description*, The Federal Lawyer, June 2004, at 29.

Seven years have passed since *Markman* and it is now apparent that the hoped-for intrajurisdictional certainty in claim construction will not be achieved without this Court's intervention. Only this Court can definitively set the law back on its proper course.

V.

CONCLUSION

Now is the time to provide clarification in the law governing patent claim construction and this case provides an excellent vehicle do to so. This Court should grant the petition for writ of certiorari, set the case for plenary review, and issue an opinion endorsing the *Markman*-based approach to patent claim construction.

DATED: July 1, 2004

Respectfully submitted,

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358 F.3d 898

United States Court of Appeals,
Federal Circuit.

LIEBEL-FLARSHEIM COMPANY and
Mallinckrodt Inc., Plaintiffs-Appellants,
v.
MEDRAD, Inc., Defendant-Cross Appellant.

Nos. 03-1082, 03-1165.

Feb. 11, 2004.
Rehearing and Rehearing En Banc Denied April 2, 2004.

J. Robert Chambers, Wood, Herron & Evans, L.L.P., of Cincinnati, OH, argued for plaintiffs-appellants. With him on the brief was Theodore R. Remaklus.

James F. Davis, Howrey Simon Arnold & White, LLP, of Washington, DC, argued for defendant-cross appellant. On the brief for the defendant-cross appellant were Frederick H. Colen and Barry J. Coyne, Reed Smith LLP, of Pittsburgh, PA. Of counsel was Kirsten R. Rydstrom, Reed Smith LLP, of Pittsburgh, PA.

Before LOURIE, BRYSON, and DYK, Circuit Judges.

BRYSON, Circuit Judge.

Appellants Liebel-Flarsheim Company and Mallinckrodt Inc. (collectively, "Liebel") filed an action against appellee Medrad, Inc., in the United States District Court for the Southern District of Ohio, No. C-1-98-858, charging Medrad with infringement of four of Liebel's patents. The patents claim certain methods and devices for use in connection with powered fluid injectors, which can be used to inject fluids into patients during medical procedures. One of the patents, U.S. Patent No. 5,456,669 ("the '669

patent"), is drawn to methods of loading powered injectors from the front. A related patent, U.S. Patent No. 5,658,261 ("the '261 patent"), is drawn to front-loadable powered injectors and to disposable front-loadable syringes for use in such injectors. The other two patents, U.S. Patent Nos. 5,662,612 ("the '612 patent") and 5,928,197 ("the '197 patent"), which are also related, are drawn to injectors and syringes for use in powered injectors, and to devices and methods for controlling the plunger drives in such powered injectors.

On motions for summary judgment, the district court ruled that Medrad did not infringe any of the asserted claims of the four Liebel patents. The district court based its summary judgment ruling on its construction of the asserted claims. In the case of the first two patents, the court concluded that the asserted claims required the use of pressure jackets around the syringes used in the powered injectors. In the case of the latter two patents, the court concluded that the asserted claims required that the powered injector directly use an electrical signal generated by a detector to compute values for various physical properties of the syringes used in the injector. Because Medrad's accused injectors did not use pressure jackets and because the electrical signals in Medrad's devices were not directly used to compute any such values, the court granted summary judgment of noninfringement as to all of the claims set forth in Liebel's complaint. The court then dismissed the counterclaims, in which Medrad alleged that the asserted claims of the four patents were invalid. The court held that the counterclaims were moot in light of the court's noninfringement ruling. We reverse the grant of summary judgment and the dismissal of the counterclaims, and we remand for further proceedings.

I

Powered injectors are used in various medical applications, such as injecting contrast agents into the vascular systems of patients who undergo certain diagnostic imaging procedures. A powered injector ordinarily uses a motor drive that is attached to a syringe plunger. The drive pulls the plunger rearward to draw contrast agent into the syringe and then drives the plunger forward to inject contrast agent through a tube and into the patient. The contrast agent is usually injected into the patient under high pressure.

A

Liebel asserted that Medrad's powered injectors infringed seven claims of the '669 patent and twenty claims of the '261 patent. The '669 and '261 patents derive from a 1991 application, Ser. No. 712,110 ("the '110 application"). Prior to the filing of the '110 application, the injectors sold by both Liebel and Medrad required that the syringes be breech loaded, i.e., loaded through the rear of the injectors. Breech loading has disadvantages, including inefficiency in the loading process and the risk of spillage and contamination that can result from disconnecting the syringe from the tube through which contrast agent is delivered to the patient. The '110 application and the patents that eventually issued from it were directed to front loading, rather than breech loading, the powered injectors.

The specifications of the '669 and '261 patents are essentially identical. Each of the embodiments of the injector described in the two patents includes a pressure jacket into which the syringe is inserted. The pressure

jacket surrounds the syringe and prevents it from breaking under the internal pressure generated when the contrast agent is injected into the patient. Based largely on the fact that the '669 and '261 patents do not contain any description of an injector that lacks a pressure jacket, the district court construed all of the asserted claims from those two patents to require a pressure jacket, even though none of the asserted claims expressly refers to a pressure jacket. The district court concluded that "the specification makes clear that the injector includes a pressure jacket." Based on that observation, the court ruled that "the asserted claims do not cover a jacketless injector, even though the asserted claims might be considered broad enough to disclose a jacketless injector when read without reference to the specification."

The parties agree that Medrad's accused devices do not use pressure jackets. Because the district court construed the claims to require pressure jackets, the district court granted summary judgment of noninfringement as to the '669 and '261 patents. Liebel appeals the claim construction of the '669 and '261 patents and the summary judgment of noninfringement based on that construction.

B

Liebel also asserts that Medrad has infringed four claims of the '612 patent and eighteen claims of the '197 patent. The '612 and '197 patents, which are related and have a common specification, address the use of syringes, including prefilled syringes, in powered injectors. Different prefilled syringes contain different amounts of fluid. In order to accommodate syringes containing different amounts of fluid and to ensure that the right amount of

fluid is injected into the patient, the powered injectors must have a way of ensuring that the injector can detect critical features of the particular syringe that is being used.

The '612 and '197 patents solve that problem by providing that the syringes have "physical indicia related to" various syringe properties that enable the injector to calibrate the amount of fluid to be injected into the patient. Each of the asserted claims requires that the syringe possess "physical indicia" that can be detected by a detector and can provide information about the syringe properties of interest. Those properties include the capacity of the syringe or the amount of fluid in the syringe ('612 patent, claims 7 and 10; '197 patent, claims 7, 10, and 27); the distance of the plunger from the end of the syringe ('197 patent, claims 1 and 4); the distance to the end of the plunger's travel position ('197 patent, claims 13 and 16); and the range of travel of the ram, which attaches to the syringe plunger and moves the plunger in and out of the syringe ('197 patent, claims 19 and 22).[1] The claims further provide that the injector's control circuitry will control the plunger, based on the particular property detected, so as to inject the correct amount of fluid from the syringe.

The common specification of the '612 and '197 patents describes each syringe as including a plunger, which is

[1] The district court noted that claim 25 of the '197 patent does not refer to the detection of physical indicia "related to" particular syringe properties, but instead recites that the control circuit "obtain[s] an offset value from physical indicia detected on the syringe." Thus, the court concluded that claim 25 requires that the information detected from the physical indicia actually constitute the offset value.

grasped by a drive jaw. The drive jaw, which is connected to a motor and control circuitry, pushes the plunger into the syringe to inject the fluid into the patient. The specification teaches that prefilled syringes may include an extender that changes the position of the plunger relative to the drive jaw. If the length of the extender is not accounted for, the drive jaw may not be properly positioned, which would cause the injector to malfunction. The specification provides that a malfunction of that kind "is avoided by storing an offset value representative of the length of the extender . . . and applying this offset value to the computed drive jaw position." '612 patent, col. 3, ll. 59-61; '197 patent, col. 3, ll. 58-60.

Medrad argued in the district court that the term "physical indicia" should be limited to indicia representing the length of the extender. The specification, Medrad asserted, describes the use of "physical indicia" only to represent the length of the extender so that a proper "offset value" can be computed and the correct position of the drive jaw can be determined. Medrad also argued that the prosecution history supports its construction of the "physical indicia" limitation.

The district court disagreed with Medrad. The court ruled that the claim language was plainly broader than Medrad's proposed construction, as the claims expressly referred to syringe features other than the length of the extender. The court further held that the specification did not clearly disavow the use of physical indicia on the syringe that represented syringe properties other than the extender length. Moreover, the court determined that the prosecution history of the patents at issue supported the broader reading of the "physical indicia" limitation.

While the district court rejected Medrad's proposed claim construction, it did not construe the claim language as broadly as Liebel urged. Instead, the court ruled that the signal generated by the detector must be directly used in the computation of particular syringe properties. The court noted that "the claim language does not describe using the electrical signal generated by the detector to ascertain information from another source and then using this ascertained information to compute syringe properties." Accordingly, the court held that physical indicia are "related to" various syringe properties only "when the information detected from the physical indicia is/are the actual syringe properties or can be directly used in the computation of the various syringe properties without reference to some other source of information."

The evidence showed that the "physical indicia" on the syringes used in the Medrad injectors consisted of a series of indents, or the absence of indents, on the surface of the syringes. Electrical circuitry in the Medrad injectors would generate an electrical signal corresponding to the particular type of syringe being used. Based on a look-up table specifying the properties of the syringe that was detected, the Medrad injectors would determine the properties of the syringe in use.

Because the detection of physical indicia on Medrad's syringes generated electrical signals that indicated the type of syringe in use, rather than directly indicating the properties of the syringe, the district court concluded that the signal was only indirectly "related to" the syringe properties referred to in the asserted claims. An indirect relationship between the physical indicia and the syringe properties in question was not within the scope of the asserted claims as the district court construed them.

Accordingly, the court ruled that Medrad's accused injectors did not infringe any of the claims of the '612 or '197 patents.

II

Liebel's appeal with respect to the asserted claims of the '669 and '261 patents turns on whether the common specification of the two patents limits the scope of the asserted claims to injectors that include pressure jackets. We hold that it does not. The asserted claims do not expressly require pressure jackets, and the common specification does not state that a pressure jacket is a required component of the inventions. Moreover, even if the original disclosure supported Medrad's contention that the invention, as originally conceived, required the use of a pressure jacket, the prosecution history of the '669 and '261 patents makes clear that the patentee drafted the asserted claims specifically to cover injectors lacking pressure jackets. In light of the applicants' clearly stated intention to cover jacketless injectors, any question regarding the support or lack of support for the claims in the original disclosure bears on the issues of priority and validity, not on the issue of claim construction. Accordingly, for the reasons more fully set forth below, we conclude that the district court erred by construing the asserted claims to require pressure jackets.

A

Claim 10 of the '669 patent is representative of the asserted claims of the '669 and '261 patents. It provides as follows:

A method of loading a tubular replacement syringe into a high pressure power injector for injecting fluid into an animal, the method comprising the steps of:

providing a power injector having:

a syringe receiving opening with a generally circular periphery therein adapted to receive a rearward end of a syringe having a generally circular rim,

a ram and a motor linked to the ram and operable to reciprocate the ram along a segment of a line projecting through the opening; and providing a hollow tubular syringe that includes:

a cylindrical body having an axis, a generally circular rim, a rearward end and a closed forward end with a fluid discharge orifice therein, and

a plunger axially slidable in the body, the syringe body being structurally capable of withstanding, at least from the rim to the orifice, fluid at an operating pressure of at least 100 psi within the interior thereof;

then:

inserting into the opening, by generally rearward axial movement of the syringe, the rearward end of the body;

rotating the syringe in the opening a fraction of a turn to thereby lock the body around the rim to the injector around the periphery of the opening; and

engaging the plunger with the ram;

then:

> energizing the motor and thereby driving the ram forward along the line and parallel to the axis to move the plunger axially forward at a programmed speed to inject the fluid at the operating pressure from within the syringe and through the orifice at a programmed rate into the animal.

Neither claim 10 of the '669 patent nor any of the other asserted claims recites a pressure jacket. The district court, however, construed the claims to require pressure jackets by focusing on the "syringe receiving opening" limitation in claim 10 (and similar language used in the other asserted claims). After finding that limitation to be ambiguous with respect to the location of the opening, the court looked to the specification and concluded that, because the syringe-receiving opening in each of the embodiments of the invention was located at the front end of a pressure jacket, the "opening" referred to in each of the asserted claims had to be located at the front end of a pressure jacket. Medrad embraces the district court's claim construction analysis and makes the more general argument that because the "pressure-jacketed injector" is the only subject matter described in the specification, that subject matter constitutes the invention itself, not simply a preferred embodiment of a broader invention.

We have had many occasions to cite one or both of the twin axioms regarding the role of the specification in claim construction: On the one hand, claims "must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). On the other hand, it is improper to read a limitation from the specification into the claims.

Arlington Indus., Inc. v. Bridgeport Fittings, Inc., 345 F.3d 1318, 1327 (Fed.Cir.2003); *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1343 (Fed.Cir.2001). Although parties frequently cite one or the other of these axioms to us as if the axiom were sufficient, standing alone, to resolve the claim construction issues we are called upon to decide, the axioms themselves seldom provide an answer, but instead merely frame the question to be resolved. We have recognized that "there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed.Cir.1998); *accord Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1307 (Fed.Cir.2003). As we have explained, "an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims 'in view of the specification' without unnecessarily importing limitations from the specification into the claims." *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed.Cir.2003); *accord Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1204-05 (Fed.Cir.2002). That problem can present particular difficulties in a case such as this one, in which the written description of the invention is narrow, but the claim language is sufficiently broad that it can be read to encompass features not described in the written description, either by general characterization or by example in any of the illustrative embodiments.

At the outset, we reject the district court's conclusion that the term "opening" should be defined as limited to an opening in a pressure jacket. The specification does not define "opening" restrictively, nor is there anything in the

specification that supports the district court's conclusion that the term is ambiguous. The asserted claims refer to the "syringe receiving opening," or simply the "opening," as having various characteristics, but none of the asserted claims state, explicitly or by necessary implication, that the opening must be formed in or in conjunction with a pressure jacket. Claim 10 of the '669 patent, for example, requires "a ram and a motor linked to the ram and operable to reciprocate the ram along a segment of a line projecting through the opening." The claim further provides that the rearward end of the syringe will be inserted into the opening and rotated in the opening to lock it in place. Thus, the "opening" must be located so that the ram reciprocates along a segment of a line projecting through the opening and so that the rear end of the syringe can be inserted into the opening and affixed to the injector at that point. But the claim language does not suggest that the "opening" must also be located at the front end of a pressure jacket.

Other asserted claims likewise refer to the location of the opening without referring to the location of the opening vis-a-vis a pressure jacket. For example, claim 19 of the '669 patent identifies the location of the opening as being "at the front end of the injector," and claims 1, 8, and 15 of the '261 patent refer, respectively, to the opening as being located "on the front [of the injector]," "at the front of the injector," and "on" the injector. Claim 27 of that patent refers to the injector housing as having "a tubular member extending forwardly from the front thereof and having a cylindrical bore therein forming the syringe receiving opening." In each case, the claim specifies the location and structure of the opening while making no mention of a pressure jacket.

In common usage, an opening is simply an aperture, and nothing in the '669 and '261 patents indicates that the term "opening" should be understood to carry with it the requirement that it must always be located in the front of a pressure jacket. Accordingly, contrary to the district court, we find no ambiguity in the term "opening" and no reason to resolve the purported ambiguity by reading that term restrictively. We therefore turn to Medrad's more general argument that the specification and the prosecution history demonstrate that the invention as a whole was limited to an injector system using a pressure jacket.

B

Medrad argues that because all the embodiments described in the common specification of the '669 and '261 patents feature pressure jackets, the claims of those patents must be construed as limited to devices that use pressure jackets. In Medrad's words, when "the subject matter claimed in the patent-in-suit is the *only* subject matter described . . . that subject matter is the invention, and not simply a 'preferred embodiment' of a broader invention."

There are several answers to Medrad's argument. The first is that this court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment. *See ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1091 (Fed.Cir.2003); *Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1377 (Fed.Cir.2003); *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1373 (Fed.Cir.2003); *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1204-05 (Fed.Cir.2002); *Teleflex, Inc. v. Ficosa N. Am.*

Corp., 299 F.3d 1313, 1327 (Fed.Cir.2002); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 n. 14 (Fed.Cir.1985) (en banc). Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using "words or expressions of manifest exclusion or restriction." *Teleflex*, 299 F.3d at 1327.

For example, in *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed.Cir.2003), the court interpreted the term "remote" broadly to include surgical procedures performed with the surgeon present in the same room as the patient, although the written description only described performing the surgical procedure without the surgeon present in the same room as the patient, because "[n]o statement in the written description [] constitute[d] a limitation on the scope of the invention." Likewise, in *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371 (Fed.Cir.2003), despite the fact that the specification discussed only a single embodiment, we held that it was improper to read a specific order of steps into method claims because the specification "nowhere [included] any disclaimer of any other order of steps, or any prosecution history indicating a surrender of any other order of steps."

In support of its contention that the claims are limited to the embodiments described in the specification, Medrad cites several of this court's cases, including *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed.Cir.2001), and *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed.Cir.1999). None of the cited cases supports Medrad's argument, however.

In *SciMed,* we stated that when the specification "makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." 242 F.3d at 1341. We concluded in *SciMed* that the claim to a two-part lumen used in balloon dilatation catheters was limited to coaxial lumens and did not include dual, side-by-side lumens. We reached that conclusion based on an explicit disclaimer of the side-by-side structure, not the mere absence of any reference to that structure in the specification. Thus, the specification discussed only the coaxial lumen structure, it characterized the side-by-side structure as inferior, and it concluded that the coaxial lumen structure was used in "all embodiments of the present invention contemplated and disclosed herein." *Id.* at 1343. Based on the language of the specification, we concluded that the *SciMed* case presented "a clear case of the disclaimer of subject matter that, absent the disclaimer, could have been considered to fall within the scope of the claim language." *Id.* at 1344. Unlike in *SciMed,* the specification in this case contains no disclaimer; all that Medrad can point to in the common specification of the '669 and '261 patents is the absence of any embodiment that lacks a pressure jacket.

In *Wang,* the claim term at issue was the term "frame" as applied to a computer application. Although the parties agreed that in the abstract that term could refer to both "character based systems" and "bit-mapped display systems," the court noted that in the context of the patent in suit, the term referred only to "character-based systems."

197 F.3d at 1382. After a close examination of the specification, the court concluded that the specification "would not be . . . understood by a person skilled in the field of the invention" to describe bit-mapped display systems as included in the applicant's invention. *Id.* Moreover, the prosecution history of the patent in suit in *Wang* showed that the inventors disclaimed a claim construction that would encompass bit-mapped display systems. *Id.* at 1383-84. *Wang* therefore does not stand for the proposition that if a patent specification describes only a particular embodiment, the claims must be limited to that subject matter. We have never read *Wang Labs* to stand for so broad a proposition, *see Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1305 (Fed.Cir.2003); *Altiris,* 318 F.3d at 1373; *Teleflex,* 299 F.3d at 1327; *SciMed,* 242 F.3d at 1341, and we decline Medrad's invitation to adopt such a rule today.

In other cases cited by Medrad, we have held that the embodiments of the invention set forth in the specification constituted the invention itself, in spite of claim language that could, in the abstract, be interpreted more broadly. *See Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1139-40 (Fed.Cir.2003); *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882-83 (Fed.Cir.2000); *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed.Cir.2000); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1301-02 (Fed.Cir.1999); *Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed.Cir.1996); *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n,* 75 F.3d 1545, 1550-51 (Fed.Cir.1996). In each of those cases, however, there were specific reasons dictating a narrow claim construction beyond the mere fact that the specification disclosed only a single embodiment or a particular structure. Thus, in *Watts,* the court held that the applicants specifically "limit[ed] the invention" to

particular structures by specifying that the invention uses those structures, and further limited the scope of the invention by distinguishing close prior art in the prosecution history. 232 F.3d at 883. Likewise, in the *Cultor* and *Biogen* cases, the court construed the pertinent claim language restrictively based on an express limiting definition of that language in the specification, *Biogen,* 318 F.3d at 1140, as well as the fact that the inventors had "repeatedly distinguished their invention from the prior art" by characterizing their invention narrowly, *Cultor,* 224 F.3d at 1330. As the court explained in *Cultor,* "Whether a claim must, in any particular case, be limited to the specific embodiment presented in the specification, depends in each case on the specificity of the description of the invention and on the prosecution history. . . . Claims are not correctly construed to cover what was expressly disclaimed." *Id.* at 1331.

The court employed the same approach in the *Toro, General American Transportation,* and *Modine Manufacturing* cases. In those cases, this court interpreted the pertinent claim language narrowly, not merely because the specification did not describe a broader embodiment, but because the specification, claim, or prosecution history made clear that the invention was limited to a particular structure. *See Toro,* 199 F.3d at 1301 (noting that the specification described particular structure as "important to the invention"); *Gen. Am. Transp.,* 93 F.3d at 770 (holding that claim language and specification made clear that openings "adjacent each of said side walls and end walls" of a rail car required the openings to be adjacent to all four walls of the railcar); *Modine,* 75 F.3d at 1551 (claim limited to a particular numerical range when

broader range was surrendered during prosecution by amendment of the specification).

In this case, the specification does not describe the invention as limited to embodiments having pressure jackets, and none of the other reasons that have been invoked for giving claims a narrow reading are present. Although all the embodiments described in the common specification of the '669 and '261 patents include a pressure jacket, the written description does not contain a clear disavowal of embodiments lacking a pressure jacket. Medrad relies on several passages from the specification in which the applicants described an embodiment that uses a pressure jacket. Those passages, however, do not expressly or by clear implication restrict the scope of the invention to injectors using a pressure jacket. The abstract of the patents states that an "animal fluid injector, replaceable syringe and method of replacement of the syringe in the injector are provided in which the syringe is loadable and unloadable into and from the injector through the open front end of a pressure jacket of the injector." Although that language can reasonably be understood as constituting a general description of the invention, the quoted passage does not suggest that a pressure jacket is an essential component of the invention, nor is there any language in that passage, or elsewhere in the specification, that disclaims the use of the invention in the absence of a pressure jacket.

The other passages from the specification on which Medrad relies provide even less support for Medrad's argument that the claims must be limited to the described embodiments. In the Summary of the Invention, the patent describes one of the objectives of the invention as being "to provide an injector wherein a used syringe can be

removed and a new one inserted in the injector without retraction of the drive from the pressure jacket, in most applications," and adds that it is "a further objective of the invention to allow for the removal of the used syringe from the jacket without disconnection of the injector tube from the syringe nozzle." '669 patent, col. 2, ll. 32-39; '261 patent, col. 2, ll. 29-36. Later in the Summary of the Invention, the patents provide: "According to the principles of the present invention, there is provided an angiographic injector having a front end loadable syringe that can be loaded into and removed from the injector pressure jacket through an opening that is provided in the front end of the pressure jacket." '669 patent, col. 2, l. 64, to col. 3, l. 1; '261 patent, col. 2, ll. 61-65. Those passages, although focusing on the use of the invention in conjunction with pressure jackets, do not disclaim the use of the invention in the absence of a pressure jacket. The fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives. *See Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1367 (Fed.Cir.2003); *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1355 (Fed.Cir.2003); *Honeywell Inc. v. Victor Co. of Japan, Ltd.*, 298 F.3d 1317, 1325-26 (Fed.Cir.2002). Moreover, the reference to the "principles of the present invention" as providing for "an angiographic injector" with a syringe that can be "loaded into and removed from the injector pressure jacket," does not limit the invention to devices that have pressure jackets any more than it limits the invention to injectors that are used for angiography. This case is therefore governed by the principle that "[a]bsent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a

particular way does not mean that the scope of the invention is limited to that context." *Northrop Grumman,* 325 F.3d at 1355; *accord Brookhill-Wilk,* 334 F.3d at 1301; *Teleflex,* 299 F.3d at 1328.

C

The second reason for rejecting Medrad's argument is that the prosecution history of the '669 and '261 patents is squarely contrary to its contention that all the claims of those two patents require injectors that use pressure jackets. The applications that matured into the '669 and '261 patents derived from the '110 application. In the prosecution of each of those applications, the applicants replaced claims that had included references to a pressure jacket with a new set of claims, many of which did not include the pressure jacket limitation. The omission of reference to a pressure jacket in many of the claims of the applications that matured into the '669 and '261 patents is a strong indication that the applicants intended those claims to reach injectors that did not use pressure jackets. Moreover, in a paper filed during the prosecution of the '261 patent, the applicants clearly stated that "[i]n the claims as amended herein, the locking structure is not necessarily at the front end of the syringe, nor is there necessarily a pressure jacket."

Both Medrad and the district court agree that, during the prosecution of the '669 and '261 patents, the applicants learned about Medrad's jacketless injector and sought to omit reference to the pressure jacket in the asserted

claims in order to encompass Medrad's injector.[2] Thus, there is no dispute as to the applicants' intentions with respect to the meaning of the asserted claims – the claims were amended to include methods and devices in which pressure jackets are not used. The only remaining question is whether the applicants failed in their effort and the pressure jacket limitation remained a part of all of the claims, even those from which the reference to the pressure jacket had been removed. We are unpersuaded by that argument, particularly in light of the applicants' express statement in the prosecution history of the '261 patent that there is not "necessarily a pressure jacket" in the claimed devices.

D

Apart from the literal language of the asserted claims and the prosecution history, the doctrine of claim differentiation provides significant added support for Liebel's claim construction. As we noted above, the '669 and '261 patents both contain claims that explicitly recite the requirement of a pressure jacket and that are dependent

[2] The district court recognized that it is not improper for an applicant to broaden his claims during prosecution in order to encompass a competitor's products, as long as the disclosure supports the broadened claims. *See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 874 (Fed.Cir.1988) (holding that it is not improper "to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application"). If the disclosure does not support the broadened claims, the applicant will not be accorded priority based on the original disclosure, and the claims may be invalidated. *See Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346 (Fed.Cir.2000); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed.Cir.1997).

from asserted independent claims that do not contain such a requirement. In the '669 patent, asserted claim 10 recites a method of loading a tubular replacement syringe into a high pressure power injector without reference to a pressure jacket. Claim 14, which depends from claim 10, adds four limitations that recite the use of a pressure jacket in the process of inserting the syringe. A comparison of claims 10 and 14 makes clear that the only significant distinction between the two is that claim 14 requires the use of a pressure jacket.

Similarly, asserted claims 1 and 18 of the '261 patent claim syringes and front-loadable power injectors without reference to pressure jackets. By contrast, claims 2 and 19, which depend from claims 1 and 18, respectively, expressly recite the use of a pressure jacket. Again, a comparison of the independent and dependent claims shows that the dependent claims differ from the independent claims only with regard to the presence of a pressure jacket in the dependent claims.

The juxtaposition of independent claims lacking any reference to a pressure jacket with dependent claims that add a pressure jacket limitation provides strong support for Liebel's argument that the independent claims were not intended to require the presence of a pressure jacket. As this court has frequently stated, the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim. *See Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed.Cir.2001); *Comark*, 156 F.3d at 1187. Although that presumption can be overcome if the circumstances suggest a different explanation, or if the evidence favoring a different claim construction is strong, the presumption is unrebutted in

this case, as Medrad has offered no alternative explanation for why the "pressure jacket" limitation is found in the dependent claims but not in the corresponding independent claims. In such a setting, where the limitation that is sought to be "read into" an independent claim already appears in a dependent claim, the doctrine of claim differentiation is at its strongest. *See Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302-03 (Fed.Cir.2003) (the presumption that an independent claim does not have a limitation that is introduced for the first time in a dependent claim "is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim"); *Wenger*, 239 F.3d at 1233 ("Claim differentiation . . . is clearly applicable when there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims."); *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574 (Fed.Cir.1985). The doctrine thus substantially undermines Medrad's contention that all of the claims of the '669 and '261 patents require the presence of a pressure jacket, even though the express requirement of a pressure jacket is found only in certain claims and not in any of the claims asserted in this case.

E

In support of its claim construction, the district court stated, without elaboration, that it is "unlikely that the specification, which was drafted for claims that disclosed an injector that included a pressure jacket, would describe an injector that does not require a pressure jacket, much

less enable one skilled in the art to make and use such a device." Medrad supplements that observation by arguing, also without elaboration, that if the asserted claims are not construed to require a pressure jacket, those claims "would be of doubtful validity."

This court has frequently alluded to the "familiar axiom that claims should be so construed, if possible, as to sustain their validity." *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed.Cir.1999) (internal quotation marks omitted). At the same time, however, the court has "admonished against judicial rewriting of claims to preserve validity." *Id.* Accordingly, unless the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous, the axiom regarding the construction to preserve the validity of the claim does not apply. *See AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1243 (Fed.Cir.2003) ("That axiom is a qualified one, dependent upon the likelihood that a validity-preserving interpretation would be a permissible one."); *Generation II Orthotics Inc. v. Med. Tech. Inc.*, 263 F.3d 1356, 1365 (Fed.Cir.2001) ("[C]laims can only be construed to preserve their validity where the proposed claim construction is 'practicable,' is based on sound claim construction principles, and does not revise or ignore the explicit language of the claims."); *Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1309 (Fed.Cir.2000) ("having concluded that the amended claim is susceptible of only one reasonable construction, we cannot construe the claim differently from its plain meaning in order to preserve its validity").

A case that is closely analogous to this one is *Texas Instruments Inc. v. United States International Trade Commission*, 871 F.2d 1054 (Fed.Cir.1989). In that case, the applicant amended a claim during prosecution, seeking

broader claim coverage that would reach a competitor's product. The International Trade Commission, in order to preserve the validity of the claim, construed the claim as being limited to the meaning it had before it was amended. This court reversed the Commission, holding that the amended claim should have been construed in accordance with the language of the amendment. The court stated: "Ambiguous claims, whenever possible, should be construed so as to preserve their validity. . . . This rule of construction, however, does not justify reading into a claim a limitation that it does not contain and that the patentee deleted from the claim during prosecution." *Id.* at 1065. The court explained that it was not improper for the applicant to amend the claim in order to cover a competitor's product that the applicant's attorney has learned about during the prosecution of the application; the court then added that it was "not permissible for the [Commission], in order to preserve the validity of the claims, to rewrite them to add a limitation that the patentee had eliminated during prosecution, and then hold that the challenged devices . . . did not infringe the rewritten claims." *Id.*

In this case, the applicants in effect drafted particular claims of the applications that matured into the '669 and '261 patents so as to omit the pressure jacket limitation that had been present in all of the claims of the parent '110 application. As in *Texas Instruments,* it would be improper to disregard the effect of that action on the scope of those claims simply because the claims, if broadly construed, might be vulnerable to a challenge to their priority and validity. Rather, because the proper construction of the claims is clear, the questions of priority and

validity are separate issues that must be separately addressed on remand.

In sum, the claims do not expressly require pressure jackets, and Medrad points to no clear disavowal of claim scope in either the written description or the prosecution history. In fact, the prosecution history indicates that the asserted claims were added to cover devices that lacked pressure jackets. For those reasons, we conclude that the district court erred in construing the claims at issue to require pressure jackets. Summary judgment of noninfringement of the '669 and '261 patents was therefore improper.

III

Medrad's appeal with respect to the asserted claims of the '612 and '197 patents turns on the proper construction of the term "physical indicia" and the relationship of the physical indicia to the properties of a syringe. Claim 7 of the '197 patent is representative of the asserted claims of the '612 and '197 patents. It provides as follows:

> An injector and syringe, comprising
>
> a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the amount of fluid in the syringe,
>
> a motor in the injector which advances and retracts the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and
>
> a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

> a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the amount of fluid in said syringe using said electrical signal and the tracked location of said motor.

A

Each of the asserted claims, except for claim 25 of the '197 patent, requires that the syringe possess "physical indicia related to" a property of the syringe. For example, claim 7 of the '197 patent, quoted above, recites "physical indicia related to the amount of fluid in the syringe," while other claims recite physical indicia related to "the distance of the plunger from an end of said syringe," "the end of travel position of an injector ram," "the range of travel of an injector ram," and "the capacity of the syringe."

Medrad argues that we should construe the term "physical indicia" as limited to features that indicate the length of the extender. To support its position, Medrad asserts that the only reference to the "physical indicia" limitation in the specification describes the "physical indicia" as providing information as to the length of the extender:

> In preferred embodiments, the offset value may be computed by querying the operator as to the capacity of the syringe and determining therefrom the appropriate offset value. The controller may be configurable so that this query is not made (for example, if the injector will not be used

> with pre-filled syringes, and therefore the offset value will not change). Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.

'612 patent, col. 3, l. 62, to col. 4, l. 3; '197 patent, col. 3, l. 61, to col. 4, l. 2.

The claim language itself does not limit "physical indicia" to indicia related to the length of the extender. Instead, the various claims explicitly state that the physical indicia are related to a variety of properties, such as the amount of fluid in the syringe, the distance of the plunger from the end of the syringe, the distance to the end of the plunger's travel position, and the range of travel of the ram. Medrad thus must overcome the "'heavy presumption' that [the claims] mean what they say." *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed.Cir.2002); *Teleflex*, 299 F.3d at 1325 ("We indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning."). As we explained above, it is improper to read limitations from a preferred embodiment described in the specification – even if it is the only embodiment – into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited. *See ACTV*, 346 F.3d at 1088; *Brookhill-Wilk*, 334 F.3d at 1301; *Altiris*, 318 F.3d at 1371, 1373; *Teleflex*, 299 F.3d at 1327. Although the passage Medrad cites describes an embodiment in which the physical indicia are related to the length of an extender, Medrad does not point to any language in the specification that expresses an intention to limit the scope of the term "physical indicia" to that embodiment.

Nor does the prosecution history support Medrad's narrow reading of the asserted claims. During the prosecution of the application that matured into the '197 patent, the examiner rejected the claims as lacking support for physical indicia related to properties other than the length of the extender. The applicants responded by explaining that various properties, such as the amount of fluid in the syringe, could be calculated from the information as to the length of the extender. The applicants went on to explain, however, that

> although the supporting specific embodiment of the invention found in the specification is disclosed in the context of compensating for the presence of a plunger extender attached to the plunger, the independent claims do not necessarily require a plunger extender, but rather are directed generally to using information from indicia on a syringe, to compensate for syringes having differing initial plunger positions, differing initial amounts of fluid, differing end-of-travel positions or ranges of travel for the ram.

Far from a clear disavowal of claim scope, the quoted passage makes clear that the application contemplated that the claims of the '197 patent would encompass "physical indicia" related to properties other than the length of an extender.

Moreover, Medrad's own version of the prosecution history of the '612 and '197 patents cuts against reading the claims at issue restrictively. The original claims in the applications for the two patents limited the term "physical indicia" to features indicating the "length of the extender" and excluded features indicating other syringe properties such as "the capacity of the syringe." According to Medrad,

when the applicants learned of Medrad's injectors they amended the claims at issue in an effort to encompass Medrad's injectors, as they did with respect to the "pressure jacket" issue. That characterization of the prosecution history, however, is unhelpful to Medrad's claim construction argument: By broadening the claims to cover Medrad's devices, the applicants covered physical indicia other than those indicating the length of an extender. The district court therefore correctly concluded that the term "physical indicia" is not limited to indicia related to the length of an extender.

Medrad further suggests in passing that the broad reading of "physical indicia" given by the district court would render the asserted claims of the '612 and '197 patents invalid for lack of a sufficient written description or enablement. As we discussed above, however, the canon that claims should be construed to preserve their validity, if possible, applies only if the scope of the claims is ambiguous. The asserted claims at issue in this case clearly cover more than the "indicia indicating the length of the extender." We therefore may not interpret the claims narrowly because of concerns about their possible invalidity. Rather, the issue of invalidity must be addressed head-on in the remand proceedings where the questions of priority, and the adequacy of the written description and enablement, will be directly presented.

B

The district court construed the claim term "related to" as requiring "the physical indicia [to be] the actual syringe properties or [indicia that can be] directly used in the computation of the various syringe properties without

reference to some other source of information." The court found the grounding for that construction in the language of the claims themselves. For example, the court reasoned that claim 7 of the '197 patent, reproduced above, requires that a detector ascertain the physical indicia and generate an electrical signal representative of those indicia. A control circuit then computes the value of the property in question, here the amount of fluid in the syringe, using that electrical signal. The district court determined that the control circuit must use the signal generated by the detector, rather than a signal generated by the control circuit, to compute the value of the property in question. The court thus construed the claims as requiring a direct relationship between the physical indicia and the property to which the physical indicia are related. That direct relationship, the district court reasoned, would exclude products, such as the Medrad injectors, that "indirectly" compute the value of the syringe property by using the electrical signal to reference a look-up table.

The language of the claims at issue does not support the interpretation adopted by the district court. The term "related to" by itself does not limit the relationship between the physical indicia and the properties in question to a direct relationship. The issue, then, is whether the claim language setting forth how the control circuit must use the electrical signal confines the relationship between the physical indicia and the syringe properties to a direct relationship. The exemplary claim quoted above requires that the "control circuit compute[] the amount of fluid in said syringe using said electrical signal." That language does not specify that the control circuit must use the electrical signal in any particular way. In the ordinary sense of the word "using," the act of employing the electrical signal to

obtain a syringe property value from a look-up table constitutes "using" the electrical signal to compute that syringe property value. Therefore, the very language relied on by the district court to restrict the scope of the claims at issue does not exclude an injector in which the control circuit uses the electrical signal to compute the syringe property indirectly, for example by using the electrical signal in conjunction with a look-up table.

Medrad asserts that during prosecution the applicants distinguished the '612 and '197 patent claims from prior art substantially similar to Medrad's accused devices and that the asserted claims therefore must be read restrictively. During prosecution of an application that matured into the '612 patent and that gave rise to a continuation that matured into the '197 patent, the examiner rejected the claims as obvious over two prior art references, McDaniel and Arthur. The McDaniel reference disclosed associating the type of syringe with its corresponding properties using a look-up table, while the Arthur reference disclosed a detector for detecting a bar code on a syringe. The examiner asserted that it would be obvious to combine the detector and bar coding of Arthur with the McDaniel device to arrive at Liebel's claims. The applicants overcame that rejection by arguing that McDaniel and Arthur should not be combined because they addressed different problems. Liebel argued that the bar code "indicia" in Arthur did not indicate any syringe properties at all, but rather provided information regarding the concentration of the medication in the syringe. McDaniel, according to Liebel, disclosed a mechanical system for determining the syringe type, such as by measuring the angle of the conical forward end of the syringe. Instead of arguing that McDaniel did not teach

detecting information "related to" syringe properties, Liebel argued that McDaniel did not teach detecting physical indicia at all. The applicants thus did not disclaim an "indirect" relationship between the physical indicia and the syringe properties.

Because both the plain language of the claims and the prosecution history do not support a claim construction limiting the relationship between the physical indicia and the syringe properties to a direct relationship, the district court erred in so ruling. It was therefore improper for the court to enter summary judgment of noninfringement of the asserted claims of the '612 and '197 patents. The district court will have to reconsider the infringement claims in light of the claim construction we have set forth above.

In view of its claim construction ruling, the district court did not need to analyze claim 25 separately from the other asserted claims of the '612 and '197 patents, other than to note that the language of claim 25 differs somewhat from that of the other claims. To the extent that Liebel continues to assert claim 25 on remand, the district court will have an opportunity to consider the proper construction of that claim in light of our interpretation of the language of the other asserted claims of the '612 and '197 patents.

IV

With respect to disposition, Liebel argues that we should direct the district court to grant summary judgment in its favor. We decline to do so. It is rare for a reviewing court, upon reversing the grant of summary judgment in favor of one party, to direct the entry of

summary judgment in favor of the other, and this is not one of those rare instances in which such a course would be appropriate. The district court is far more familiar with the record in this case than we are and is in a much better position to determine whether, based on the claim construction issues addressed above, summary judgment in Liebel's favor would be appropriate. Moreover, Medrad points out that there are unresolved issues of infringement that would have to be addressed before a final judgment of infringement could properly be entered. We therefore reverse the entry of summary judgment in Medrad's favor, but we do not direct the entry of summary judgment for Liebel.

As to Medrad's cross-appeal, we agree that Medrad's invalidity counterclaims are not moot. Because we have reversed the order granting summary judgment of noninfringement, the legal basis for the district court's mootness ruling is no longer in place. The invalidity counterclaims are therefore again presented for decision, and we assume that the district court will address the counterclaims on remand if Medrad continues to press them.

REVERSED and REMANDED.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

LIEBEL-FLARSHEIM COMPANY, and MALLINCKRODT INC.	)	Civil Action No. C-1-98-858
Plaintiffs,	)	Judge Sandra S. Beckwith Magistrate Judge Jack Sherman, Jr.
v.	)	
MEDRAD, INC.,	)	
Defendant.	)	

JUDGMENT IN A CIVIL CASE

(Filed Oct. 31, 2002)

This is an action for infringement of U.S. Patent Nos. 5,456,669, 5,658,261, 5,662,612 and 5,928,197; violation of the antitrust laws of the United States; and tortious interference with existing and prospective business relations.

On October 18, 2001, this Court entered an Order (Doc. No. 247) granting summary judgment of non-infringement for defendant Medrad, Inc. on Counts I and II of the Fourth Amended Complaint (Doc. No. 30) with respect to U.S. Patent Nos. 5,456,669 and 5,658,261.

On February 19, 2002, this court entered an Order (Doc. No. 271) granting summary judgment of non-infringement for defendant Medrad, Inc. on Counts III and IX of the Fourth Amended Complaint (Doc. No. 30).

On May 14, 2002, this Court entered an Order (Doc. No. 284) dismissing, without prejudice, as moot defendant Medrad, Inc.'s counterclaims of invalidity, unenforceability

and unclean hands, laches, and estoppel as stated in Counterclaim paragraph 10, 11 and 12 of its Amended Answer and Amended Counterclaim (Doc. No. 82).

On October 9, 2002, the parties fully and finally settled Counts IV-VIII of the Fourth Amended Complaint.

It is hereby ORDERED AND ADJUDGED that judgment is entered for defendant Medrad, Inc. on Counts I and II of the Fourth Amended Complaint for the reasons set forth in the Order entered October 18, 2001 (Doc. No. 247), that judgment is entered for defendant Medrad, Inc. on Counts III and IX of the Fourth Amended Complaint for the reasons set forth in the Order entered February 19, 2002 (Doc. No. 271), that Counts IV-VIII are dismissed with prejudice by agreement and that defendant Medrad, Inc.'s counterclaims as to invalidity, unenforceability and unclean hands, laches and estoppel as stated in its Amended Answer and Amended Counterclaim are dismissed without prejudice as moot for the reasons set forth in the Order entered May 14, 2002 (Doc. No. 284).

Dated this 30th day of October, 2002.

Clerk of Court.

By: /s/ Sandra S. Beckwith

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

Liebel-Flarsheim Co.	:	
Plaintiff,	:	
vs.	:	Case C-1-98-858
Medrad Inc.,	:	
Defendant.	:	

ORDER

(Filed Oct. 18, 2001)

This matter is before the Court on multiple motions for partial summary judgment. In this Order, the Court will address the motions filed under Doc. Nos. 57, 162, 164, 167, 168, and 169.

I. GENERAL BACKGROUND

The patents at issue in this case, United States Patent No. 5,456,669 ("the '669 patent"), United States Patent No. 5,658,261 ("the '261 patent"), United States Patent No. 5,662,612 ("the '612 patent"), and United States Patent No. 5,928,197 ("the '197 patent"), are part of a series of patents that relate to medical devices known as powered injectors which deliver contrast agents[1] from a syringe into a patient's bloodstream for

[1] In a number of diagnostic procedures, such as angiography, computed tomography, ultrasound, and magnetic resonance imaging, the image obtained may be substantially enhanced through the use of a

(Continued on following page)

certain medical diagnostic procedures. (Doc. No. 30, Exhs. 1-4). The specific patents at issue in this case involve two developments in the field of power injectors (1) the front-loadable power injector and (2) automatic control of the plunger driver during the injection process.

A. Front-Loadable Power Injectors

When the original '110 application was filed, the powered injectors sold by both Plaintiff Liebel-Flarsheim Company ("L-F") and Defendant Medrad, Inc. ("Medrad") required that the syringe be inserted in the injector by a breech-load method. However, loading of the syringe by the breech-load method was cumbersome, time-consuming, and inefficient, and this method presented a cleanliness problem and posed a safety hazard.

In the late 1980's, L-F began a brainstorming process that culminated in the invention of a front-loadable powered injector system that eliminated the disadvantages inherent in the breech-loading power medical injectors and provided benefits in terms of use, speed, efficiency, sterility, and cleanliness.

On June 7, 1991, L-F filed its first patent application, Application Serial No. 07/712,110 ("the '110 application") on its CT injection system with a front-loadable syringe. (Doc. No. 57, Exh. 7). The '669 and '261 patents, entitled "Method of Front Loading an Injector and Injecting Fluid into Animals Therewith" and "Disposable Front Loadable Syringe," respectively, issued from a series of divisional

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contrast agent, *i.e.*, a pharmaceutical that is injected into the body of the patient.

applications originating with the '110 application.[2] (Doc. No. 30, Exhs. 1, 2).

At the time the '110 application was filed, all power injectors that used disposable plastic syringes had components known as pressure jackets, which are hollow cylindrical tubes attached to the front of the injector that surround the syringe. (Doc. No. 57, Exh. 8 – Goethel Depo., p. 465, Exh. 9 – Fago Depo., p. 103, Exh. 13, Dieterlen Depo., p. 141, Exh. 14 – Neer Depo, p. 135). During the development of its front-loadable injector system, L-F considered the idea of eliminating the pressure jacket. (Doc. No. 57, Exh. 9 – Fago Depo., p. 83, Exh. 13 – Dieterlen Depo., p. 63). After running several preliminary tests, L-F chose not to develop a jacketless injector system. (Doc. No. 57, Exh. 9 – Fago Depo., pp. 83-84, Exh. 13 – Dieterlen Depo., p. 63).

At a trade show in November in 1992, Medrad introduced the first pressure jacketless, front-loading CT injector system for disposable syringes. (Doc. No. 57, Exh. 11, ¶ 2). This system neither required nor used a pressure jacket. (*Id.*). All of Medrad's injector systems that were or are front loaded did not and do not use or require a pressure jacket. (*Id.* at ¶ 4). After Medrad introduced its jacketless injector, L-F amended the '669 and '261 patent

[2] The patent application for the '669 patent was filed on November 30, 1993, and issued on October 5 1995. The patent application for the '261 patent was filed on April 6, 1995, and issued on August 19, 1997. Because the '669 and '261 were divisional applications originating with the '110 application, they have an effective filing date of June 7, 1991, the filing date of the '110 applications. Furthermore, as divisional applications, the '669 and '261 patents have the same specifications and drawings.

applications, removing references to a pressure jacket in certain claims.[3] (Doc. No. 57, Exhs. 22, 26).

B. Automatic Control of Plunger Drivers

On June 26, 1995 and August 28, 1997, L-F filed patent applications that issued as the '612 patent and the '197 patent, respectively, relating to the automatic control of plunger drives in powered medical injector systems.[4] (Doc. 30, Exhs. 3, 4). At the time the patents were filed, the use of pre-filled disposable syringes was a recent advancement in the field of medical injector systems. These pre-filled syringes differed in capacity depending upon the medical procedure being performed.

The '612 and '197 patents, both titled "Controlling Plunger Drives for Fluid Injections in Animals", disclose a powered medical injector that automates the injection of pre-filled syringes. (Doc. No. 30, Exhs. 3, 4). The injector claimed in the patents includes structure and control circuitry that detects physical indicia on a syringe that relates to physical properties of the syringe. Based on these physical properties, the control circuitry of the injector automatically controls the injection process.

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[3] The '669 patent was amended on September 12, 1994, and the '261 patent was amended on April 6, 1995.

[4] The '612 patent issued on September 2, 1997 and the '197 patent issued on July 27, 1999. The '612 and '197 patents are continuations of a patent that was filed on November 27, 1993, but was subsequently abandoned. (Doc. No. 167, Exh. 4). Therefore, the '612 and '197 patents claim an effective filing date of November 24, 1993. Furthermore, as continuation applications, the '612 and '197 patents have the same specifications and drawings.

L-F initiated this lawsuit on November 13, 1998, claiming that Medrad, through its manufacture, use, marketing, and/or sale of various injectors and syringes, infringed, contributorily infringed, and/or induced infringement of the '669, '261, '612, and '197 patents. (Doc. Nos. 1, 4, 5, 23, 30). Medrad denied L-F's claims and counterclaimed seeking a declaratory judgment that Medrad does not infringe the '669, '261, '612, and '197 patents, that such patents are invalid, that such patents are void and unenforceable due to L-F's inequitable conduct, and that L-F is precluded from asserting its claims by virtue of unclean hands, laches and/or equitable estoppel. (Doc. Nos. 24, 25, 39).

Numerous partial summary judgment motions have been filed in this matter, including a motion for claim construction. Accordingly, on July 23, 2001, this Court conducted a *Markman* hearing at which counsel for both parties presented evidence. The Court is now prepared to rule on the following motions for partial summary judgment:

1. Plaintiff's Motion for Partial Summary Judgment of Claim Construction (Doc. 164)

2. Defendant's Motion for Partial Summary Judgment of Invalidity for Lack of Enablement of the Asserted Claims of the '669 and '261 Patents (Doc. 168)

3. Defendant's Motion for Partial Summary Judgment of Invalidity and Non-Infringement of the Asserted Claims of the '669 and '261 Patents (Doc. 57)

4. Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612

and '197 Patents Because Defendant Practices its Own Patent Which is Prior Art to the Asserted Patents (Doc. 162)

5. Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. 167).

6. Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. 169).

II. SUMMARY JUDGMENT STANDARD

Summary Judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). The party opposing a properly supported summary judgment motion "'may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial.'" *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (quoting *First Nat'l Bank of Arizona v. Cities Serv. Co.*, 391 U.S. 253 (1968)). The Court is not duty bound to search the entire record in an effort to establish a lack of material facts. *Guarino v. Brookfield Township Trs.*, 980 F.2d 399, 404 (6th Cir. 1992); *Inter-Royal Corp. v. Sponseller*, 889 F.2d 108, 111 (6th Cir. 1989), *cert. denied, Superior Roll Forming Co. v. Inter-Royal Corp.*, 494 U.S. 1091 (1990). Rather, the burden is on the non-moving party to "present affirmative evidence to defeat a properly supported motion for summary judgment. . . ," *Street v. J.C. Bradford & Co.*, 886 F.2d 1472,

1479-80 (6th Cir. 1989), and to designate specific facts in dispute. *Anderson*, 477 U.S. at 250. The non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Electric Industries Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The court construes the evidence presented in the light most favorable to the non-movant and draws all justifiable inferences in the non-movant's favor. *United States v. Diebold Inc.*, 369 U.S. 654, 655 (1962).

The court's function is not to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial. *Anderson*, 477 U.S. at 249. The Court must assess "whether there is the need for trial – whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Id.* at 250. "If the evidence is merely colorable, . . . , or is not significantly probative, . . . , the court may grant judgment." *Anderson*, 477 U.S. at 249-50. (citations omitted). The Supreme Court has held that:

> The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict . . .

Id. at 252. The "'mere possibility'" of a factual dispute will not suffice. *Mitchell v. Toledo Hospital*, 964 F.2d 577, 582 (6th Cir. 1992) (quoting *Gregg v. Allen-Bradley Co.*, 801 F.2d 859, 863 (6th Cir. 1986)).

Summary judgment is not appropriate simply because the weight of the evidence favors the moving party. *Poller v. Columbia Broadcasting Systems, Inc.*, 368 U.S. 464, 472 (1962). The issue of material fact required "to entitle a party to proceed to trial is not required to be resolved conclusively in favor of the party asserting its existence; rather, all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Cities Serv. Co.*, 391 U.S. at 288-89.

Although summary judgment must be used with extreme caution since it operates to deny a litigant his day in court, *Smith v. Hudson*, 600 F.2d 60, 63 (6th Cir. 1979), (citations omitted), *cert. dismissed*, 444 U.S. 986 (1979), the United States Supreme Court has stated that the "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (citations omitted).

III. PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF CLAIM CONSTRUCTION (DOC. 164)

In this motion, L-F moves the Court for construction of the following claim terms and claim language:

- "syringe receiving opening" or "opening"
- "high pressure"
- none of the asserted claims of the '669 patent and none of the asserted claims of the

'261 patent requires that the injector include a pressure jacket

- "physical indicia"
- "motor" and "tracks" the location of said motor"

(Doc. No. 164.) Medrad has filed a memorandum in opposition (Doc. No. 172) to which L-F has filed a reply (Doc. No. 182).[5] [6]

A. Law on Claim Construction

When construing a patent claim, the court must first consider the intrinsic evidence, i.e., the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir. 1996);

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[5] The Court also reviewed Medrad's Motion to File a Sur-Reply (Doc. No. 191) and L-F's memorandum in opposition (Doc. No. 197). Additionally, the Court reviewed L-F's Motion to File a Post-Claim Construction Hearing Memorandum (Doc. No. 223), Medrad's memorandum in opposition (Doc. No. 230), and L-F's reply (Doc. No. 236).

[6] L-F and Medrad also presented arguments addressing the issue of interpretation of the claim terms in Medrad's Motion for Partial Summary Judgment of Invalidity and Non-infringement of the '669 and '261 Patents (Doc. No. 57), L-F's Response to that motion (Doc. No. 84), and Medrad's Reply (Doc. No. 99); in Medrad's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the '612 and '197 Patents (Doc. No. 167), L-F's Response to that motion (Doc. No. 174), and Medrad's Reply (Doc. No. 184); in Medrad's Motion for Partial Summary Judgment of Invalidity for Lack of Enablement of the '669 and '261 Patents (Doc. No. 168); L-F's Response to that motion (Doc. No. 175), and Medrad's Reply (Doc. No. 187); in L-F's Motion for Partial Summary Judgment of Infringement (Doc. No. 169), Medrad's Response to that motion (Doc. No. 176), and L-F's Reply (Doc. No. 185). The Court reviewed the arguments presented in each of these documents when construing the claim terms.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir. 1995), *aff'd*, 517 U.S. 370 (1996)). Extrinisic evidence may be considered if the intrinsic evidence does not resolve an ambiguity in a challenged claim. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed.Cir. 1999). However, "the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Karlan Technology Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971 (Fed.Cir. 1999). The court may receive extrinsic evidence to educate itself about the invention and the relevant technology. *Id.*

In claim construction, the court first considers the language of the claim. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed.Cir. 2001); *Johnson Worldwide Assocs.*, 175 F.3d at 989. The court should give claim terms their ordinary and customary meaning unless the specification or prosecution history provides a special, different meaning or definition. *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed.Cir. 2000); *see Johnson Worldwide Assocs.*, 175 F.3d at 989. The court will ordinarily give general descriptive terms their full meaning and will not add modifiers to broad terms standing alone. *Johnson Worldwide Assocs.*, 175 F.3d at 989. The court "must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms. *Id.* Where certain words have no specialized meaning to persons of skill in the art, "the ordinary meaning of those words to those skilled in the art controls . . . , unless the evidence indicates that the inventor used them differently." *See Karlin Technology*, 177 F.3d at 971; *Toro Co. v. White Consolidated Industries,*

Inc., 199 F.3d 1295, 1299 (Fed.Cir. 1999) (quoting *Hoechst Celanese Corp. v. B.P. Chemicals Ltd.*, 78 F.3d 1575, 1578 (Fed.Cir. 1996), *cert. denied*, 519 U.S. 911 (1996)).

In addition to interpreting a claim by the language used, the court also must read claims in view of the specification. *Markman*, 52 F.3d at 979 (citations omitted); *see Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir. 1998) (stating that because a court must understand and interpret the inventor's words as they would be understood and interpreted by a person in that field of technology, the court must review the same resources as that skilled person would review, *i.e.*, the patent specification and the prosecution history). The specification contains a written description of the invention that must enable a person of ordinary skill in the art to make and use the invention. *Markman*, 52 F.3d at 979. Furthermore, the description may define terms used in the claims. *See id.* The court reviews the specification to determine whether the patentee used terms in a manner consistent with their ordinary meaning. *DeMarini Sports, Inc. v. Worth Inc.*, 239 F.3d 1314, 1323 (Fed.Cir. 2001).

Although claims are interpreted in light of the specification, this does not mean that everything stated in the specification must be read into all the claims. *SRI Int'l v. Matsushita Electric Corp.*, 775 F.2d 1107, 1121 (Fed.Cir. 1985) (quoting *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957 (Fed.Cir. 1983), *cert. denied*, 469 U.S. 835 (1984)). While the written description may help the court construe a claim term, the court may not read into the claim limitations, examples, or embodiments appearing only in the written description. *Kraft Foods*, 203 F.3d at 1366. "[I]nterpreting what is *meant* by a word *in* a claim 'is not to be confused with adding an extraneous limitation appearing in the

specification, which is improper.'" *Intervet America, Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed.Cir. 1989) (quoting *E.I. Du Pont De Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed.Cir. 1988), *cert. denied*, 488 U.S. 986 (1988)). The claims measure the invention. *SRI Int'l*, 775 F.2d at 1121 (citations omitted).

However, "'[c]laims are not interpreted in a vacuum but are part of and are read in light of the specification.'" *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1341 (Fed.Cir. 2001) (quoting *Slimfold Mfg. Co. v. Kinkead Industries, Inc.*, 810 F.2d 1113, 1116 (Fed.Cir. 1987)). "One purpose for reviewing the specification is to determine whether the patentee has limited the scope of the claims." *Watts v. XL Systems, Inc.*, 232 F.3d 877, 882 (Fed.Cir. 2000). "Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." *SciMed Life Systems*, 242 F.3d at 1341.

In addition to the specification, a court considers the prosecution history to determine the true meaning of the language used in the patent claim. *Markman*, 52 F.3d at 980. However, the court may not use the prosecution history to "'enlarge, diminish, or vary' the limitations in the claims." *Id.* (quoting *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 227 (1880)); *see also*, *Intervet America*, 887 F.2d at 1054. The court considers the prosecution history to determine whether or not the patentee made any express representations in obtaining the patent

regarding the scope and meaning of the claims. *DeMarini Sports*, 239 F.3d at 1323.

With these principles in mind, the Court will proceed with the requested claim construction of the '669, '261, '612, and '197 patents.

B. "Syringe Receiving Opening" or "Opening"/ Requirement of a Pressure Jacket

In this motion for partial summary judgment, L-F requests that the Court interpret the terms "syringe receiving opening" and "opening" as they appear in the asserted claims of the '669 and '261 patents.[7] As the following analysis demonstrates, the construction of these terms is closely intertwined with L-F's contention that the injector referenced in the asserted claims of the '669 and '261 patents does not require a pressure jacket. The Court will, therefore, analyze these issues together.

L-F proposes that the terms "syringe receiving opening" and "opening" refer to "an opening in an injector for receiving a syringe." (Doc. No. 164, p. 1). Medrad contends that the terms refer to the "open end of a pressure jacket." (Doc. No. 172, p. 16).

The difference in the parties' interpretations of these terms is significant. On the issue of non-infringement of the asserted claims, Medrad argues that the accused products do not infringe the '669 and '261 patents because both patent specifications describe an injector that requires a pressure

[7] The asserted claims are 10-11, 13, 16-19 of the '669 patent and 1, 8, 9, 11-13, 15-16, 18, 22, 27-28, 30-32, 34-37 of the '261 patent.

jacket.[8] (Doc. No. 57, p. 19). Medrad's accused injectors are jacketless. L-F, on the other hand, argues that the term "pressure jacket" does not appear in the asserted claims, and thus, the claims do not describe an injector that requires a pressure jacket. (Doc. No. 164, p. 23). In response, Medrad has argued that the asserted claims contain the terms "syringe receiving opening" or "opening," which, in order to preserve the validity of the patents, must be interpreted as the opening of a pressure jacket. (Doc. No. 57, p. 18). Therefore, according to Medrad, the claims describe a device that requires a pressure jacket. (*Id.*).

The Court begins its analysis where all claim construction begins – the language of the claim. *See Interactive Gift Express*, 256 F.3d at 1331. With respect to the asserted claims, "syringe receiving opening" and "opening" are described as follows:

- "a syringe receiving opening with a generally circular periphery therein adapted to receive a rearward end of a syringe having a generally circular rim"
  '669 patent, Claim 10

- "an opening at the front end of the injector dimensioned to receive the back end of a disposable syringe . . . "
  '669 patent, Claim 19

[8] It should be noted that the '669 and '261 patents do not claim the invention of a front-loadable injector. Rather, the '669 patent claims a method of front loading an injector and injecting fluid and the '261 patent claims a device of a front-loadable syringe. However, the claims of the '669 and '261 patents describe the injector with some specificity.

- "a circular syringe receiving opening therein bounded by a circular annular periphery . . . " '261 patent, Claim 11

- "a circular syringe receiving opening bounded by a circular annular periphery . . . " '261 patent, Claim 30

(Doc. No. 30, Exhs. 1, 2). Clearly, this language describes a circular opening sized to accommodate the rear end of a syringe. Moreover, such a construction is supported by the ordinary dictionary definition of the terms. Webster's defines a "syringe" as "a device used to inject fluids into or withdraw them from the body or its cavities . . . " Webster's Third New International Dictionary at 2322 (1971). "Receive" is defined as "to take in: act as a receptacle or container for . . . ", and "opening" is defined as "something that is open: as a (1): BREACH, APERTURE . . . (2): an open width: SPREAD, SPAN . . . " *Id.* at 1580, 1894. Thus, the dictionary definition of a "syringe receiving opening" is an open width able to take in a device used to inject fluids into or withdraw them from the body. The language of the claims requires that this "open width" be circular.

The real issue dividing the parties is not the characteristics of a "syringe receiving opening" or "opening" but rather the location of such an opening. L-F, by asking the Court to conclude that the asserted claims involve an injector that does not require a pressure jacket, is asking the Court to conclude that the "syringe receiving opening" may be located anywhere, including the front-end of a pressure jacket.[9] Medrad argues, on the other hand, that

[9] Based on the language of Claim 19 of the '669 patent ("an opening at the front end of the injector), it appears, at the very least, such an opening would be somewhere on the front of the injector.

the injector described in the asserted claims requires a pressure jacket; therefore, the "syringe receiving opening" must be located at the front-end of the required pressure jacket.

The parties do not dispute that the asserted claims do not contain the term "pressure jacket". However, the absence of the term "pressure jacket" does not necessarily lead to the conclusion that the injector referred to in the asserted claims does not require a pressure jacket. While the claim language does not require a pressure jacket. While the claim language does not explicitly require a pressure jacket, neither does it explicitly describe a jacketless injector.[10] Because the claim language is ambiguous with respect to the requirement of a pressure jacket, the Court must conduct a review of all the intrinsic evidence (the claim language, the specification, and the prosecution history) to determine whether the injector described in the asserted claims requires a pressure jacket. *See Interactive Gift Express*, 256 F.3d at 1331.

Even the most cursory reading of the specification of the '669 and '261 patents[11] reveals that the injector described in the specification includes a pressure jacket:

> An animal fluid injector, replaceable syringe and method of replacement of the syringe in the injector are provided in which the syringe is

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[10] At the time the patent applications for the '669 and '261 patent were filed, injectors that used disposable syringes included pressure jackets. (Doc. No. 57, Exh. 8 – Goethel Depo., p. 465, Exh. 9 – Fago Depo., p. 103, Exh.13, Dieterlen Depo., p. 141, Exh. 14 – Neer Depo, p. 135).

[11] As explained in detail in footnote 2, the '669 and '261 patents have the same specification.

> loadable and unloadable ***into and from the injector through the open front end of a pressure jacket of the injector*** . . .
> '669 patent and '261 patent, Abstract
>
> * * *
>
> It is an additional objective of the present invention to provide an injector wherein a used syringe can be removed and a new one ***inserted in the injector without retraction of the drive from the pressure jacket in most applications***. It is a further objective of the invention to allow for ***the removal of the used syringe from the jacket*** without disconnection of the injector tube from the syringe nozzle.
> '669 patent, col. 2, lines 32-39
> '261 patent, col. 2, lines 30-37

(Doc. No. 30, Exhs. 1, 2) (emphasis added). Not only does the specification contemplate an injector that includes a pressure jacket, a pressure jacket appears to be an essential component of the injector. According to the specification, the purpose of the pressure jacket is to reinforce the walls of the syringe used in the injector against pressures placed upon it by the injector:

> The syringe 32 is disposable, and includes walls which will withstand only moderate or low pressure. The walls are usually outwardly deformable under operating pressures, particularly pressures of 300 psi or more. Such higher pressures are necessary to overcome pressure drops through the injection tubing at higher flow rates, which are often desirable. ***The jacket 31 is made of a stronger transparent material that will withstand the operating pressures. When the syringe 32 is contained in the jacket 31, it is surrounded by the jacket 31***

> ***and supported by the jacket 31 against expansion caused by the fluid pressure within as the syringe 32 expands against the jacket wall.***
> '669 patent, col. 7, lines 15-26
> '261 patent, col. 7, lines 10-21
>
> * * *
>
> The pressure jacket 31 has a generally cylindrical inner bore . . . The bore 33 is dimensioned so as to receive through the remote end 35 the disposable syringe 32 and ***to support the syringe against expansion from fluid pressure within such fluid pressure may range to more than a thousand psi.***
> '669 patent, col. 7, lines 26-33
> '261 patent, col. 7, lines 22-29
>
> * * *
>
> To provide this front end loadable feature, the syringes of the preferred and illustrated embodiments of the present invention are provided with a front wall that is pressure restraining, that is, of sufficient strength to support the front of the syringe against the expected pressures within the syringe, and ***that is securable to the front end of the pressure jacket so as to complete the pressure restraining enclosure of the syringe within the pressure jacket and hold the syringe in the jacket.***
> '669 patent, col. 3, lines 1-9
> '261 patent, col. 2, lines 65-67 to col. 3, lines 1-7

(Doc. No. 30, Exhs. 1, 2) (emphasis added). Furthermore, the pressure jacket is an integral component of the injector described in the specifications. Other features of the injector, including the syringe used in the injector, rely on

the existence of a pressure jacket, and the specification does not describe how such features would work without the existence of a pressure jacket. (Doc. No. 30, Exh. 1, '669 patent: col. 2, lines 53-56; col. 3, lines 1-9; col. 7, lines 35-48; col. 8, lines 45-65; col. 9, lines 45-55; col. 10, lines 45-51). Quite simply, the specification fails to describe the components, design, or operation of an injector that does not include a pressure jacket.

In light of the specification, the fact that the asserted claims do not mention a pressure jacket simply does not support the conclusion that the asserted claims describe a jacketless injector. In *SciMed Life Systems*, 242 F.3d at 1341, the court concluded that:

> [w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.

In the present case, the opposite is true. The specification makes clear that the injector includes a pressure jacket. Accordingly, the Court concludes that the asserted claims do not cover a jacketless injector, even though the asserted claims might be considered broad enough to disclose a jacketless injector when read without reference to the specification. *See also, Watts*, 232 F.3d at 882-83 (claim that described pipe joints that could be "sealingly connected" limited to a misaligned taper angle connection method because specification discussed "the present invention" only in terms of the misaligned taper angle connection method); *Wang Labs., Inc. v. America Online, Inc.*, 197 F.3d 1377, 1382 (Fed.Cir. 1999) (court limited a

computer system claim term ("frame") to character-based systems noting that the "only system that is described and enabled in the [patent] specification uses a character-based protocol" and that "references to other known protocols [did] not describe them as included in the applicant's invention, and that the specification would not be so understood by a person skilled in the field of the invention.").

Although L-F does not appear to disagree with the conclusion that the specification describes an injector that includes a pressure jacket, it maintains that a pressure jacket is not a required element of the injector described in the asserted claims. (Doc. No. 164, pp. 18-19). L-F argues that the specification of the '669 and '261 patents merely discloses a preferred embodiment of a front-loadable injector that includes a pressure jacket. (*Id.*). L-F points to the following excerpt, which appears immediately prior to the claims of the '669 and '261 patents:

> [t]he invention has been described in the context of its preferred embodiments. It will be appreciated by those skilled in the art that variations and alternatives to the embodiments described may be employed without departing from the principles of the present invention. Accordingly, this patent is not intended to be limited except by the scope of the following claims: . . .
> '669 patent, col. 13, lines 52-58
> '261 patent, col. 13, lines 54-60

(Doc. No. 30, Exhs. 1, 2). L-F correctly notes that a patent's claims are not limited to the preferred embodiment included in the specification, unless the language of the claims so limits them. *See Karlin Technology*, 177 F.3d at 973; *see also SRI Int'l*, 775 F.2d at 1122 (quoting *Smith v.*

Snow, 294 U.S. 1, 11 (1935)). Because the asserted claims do not mention a pressure jacket, L-F argues that the limitation of a pressure jacket cannot be read into the asserted claims of the '669 and '261 patents. (Doc. No. 164 at 18-19).

However, as Medrad correctly argues, a review of the specification reveals that every embodiment disclosed in the asserted patents requires a pressure jacket. An injector that includes a pressure jacket is not a preferred embodiment of the injector. As the following excerpt demonstrates, the only injector contemplated by the specification is an injector with a pressure jacket:

> According to the ***principles of the present invention***, there is provided an angiographic injector having a front end loadable syringe that can be ***loaded into and removed from the injector pressure jacket*** through an opening that is provided in the front end of the pressure jacket. To provide this front end loadable feature, the ***syringes of the preferred and illustrated embodiments of the present invention are provided with a front wall*** that is pressure restraining . . . and ***that is securable to the front end of the pressure jacket*** . . .
> '669 patent, col. 2, lines 64-67 to col. 3, lines 1-4
> '261 patent, col. 2, lines 61-67 to col. 3, line 1

(Doc. No. 30, Exhs. 1, 2) (emphasis added). Thus, a pressure jacket is a required element of the injector described in the asserted claims. *See Modine Mfg. Co. v. United States Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed.Cir. 1996), *cert. denied, Showa Aluminum Corp. v. Modine Mfg.*, 518 U.S. 1005 (1996) ("[W]hen the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope

broader than that embodiment."); *Wang Labs*, 197 F.3d at 1382-83 (scope of claims limited to the only embodiment described in the specification).

The prosecution history also supports the conclusion that the asserted claims of the '669 and '261 patents involve an injector that requires a pressure jacket. The original applications which led to the '669 and '261 patents were filed on November 30, 1993 and April 6, 1995, respectively. (Doc. No. 57, Exhs. 23, 25). In the applications, all the independent claims included a pressure jacket and no dependent claims provided for the removal or elimination of the pressure jacket.

On September 12, 1994, L-F amended certain claims of the application that resulted in the '669 patent. (Doc. No. 57, Exh. 22). L-F removed the references to the pressure jacket in those claims. (*Id.*; Doc. No. 57, Exh. 2). Similarly, on April 6, 1995, L-F amended certain claims of the application that resulted in the '261 patent. (Doc. No. 57, Exh. 26). Again, L-F removed the references to the pressure jacket in those claims. (*Id.*; Doc. No. 57, Exh. 3). The specifications for the '669 and '261 patents remained the same.

It is undisputed that L-F amended the claims after it learned of Medrad's invention of a jacketless injector. Regarding the amendment of claims in light of a competitor's product, the Federal Circuit has held that:

> there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the

> applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course. . . .

Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed.Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989) (citing *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235 (Fed.Cir. 1985)). Thus, despite Medrad's argument to the contrary, L-F did nothing improper in amending the claims submitted in the original applications.

Although the fact that the original claims of the '669 and '261 patents were amended has no bearing on the Court's analysis, the substance of the original claims is relevant to its analysis. The original claims described an injector that required a pressure jacket. The specification was drafted for claims that disclosed an injector that required a pressure jacket, and this specification was not amended when the original claims were amended. It is unlikely that the specification, which was drafted for claims that included a pressure jacket, would describe an injector that does not require a pressure jacket, much less enable one skilled in the art to make and use such a device.

L-F argues that the prosecution history actually supports a conclusion that the injector described in the asserted claims does not require a pressure jacket. In an April 22, 1996, amendment to the '261 patent, L-F stated:

> In the claims as amended herein, the locking structure is not necessarily at the front end of the syringe, nor is there necessarily a pressure jacket . . .

(Doc. No. 84, Exh. 4(b), MED 000189). Based on this excerpt alone, L-F argues that "[t]he Patent Office Examiner understood that the claims of the '261 patent were directed to the syringe/injector locking structure either at the front or the rear of the syringe and with or without a pressure jacket." (Doc. No. 164, p. 20). This Court cannot accept such an argument. When faced with a similar argument in *DeMarini Sports*, 239 F.3d at 1326, the court held that "[d]rawing inferences of the meaning of claim terms from an examiner's silence is not a proper basis on which to construe a patent claim . . . " As in *DeMarini Sports*, it is L-F, not the Examiner, who commented on the absence of a pressure jacket. The Examiner did not comment either way on the existence of a pressure jacket.

Finally, L-F proposes that the doctrine of claim differentiation prevents the Court from interpreting the asserted claims as requiring pressure jackets. (Doc. No. 164, pp. 16-18). The doctrine of claim differentiation is based "on the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Karlin Technology*, 177 F.3d at 971-72. However, courts cannot use the doctrine of claim differentiation to "broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence." *Multiform Desiccants*, 133 F.3d at 1480. The doctrine of claim construction "only creates a presumption that each claim in a patent has a different scope; it is 'not a hard and fast rule of construction.'" *Kraft Foods*, 203 F.3d at 1368 (quoting *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed.Cir. 1998)); *Karlin Technology*, 177 F.3d at 972 (stating that the doctrine of claim differentiation is not a rigid rule).

According to L-F, the doctrine of claim differentiation precludes the Court from reading a pressure jacket requirement into claims 10 and 19 of the '669 Patent, as this requirement expressly appears in claim 14 which depends from claim 10.[12] (Doc. No. 164, p. 16-18). Likewise, L-F asserts that claim differentiation precludes the Court from reading a pressure jacket requirement into claims 1 and 18 of the '261 patent as this requirement expressly appears in dependent claims 2 and 19.[13] (*Id.*).

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[12] Claim 14 of the '669 patent provides as follows:

The method of claim 10 wherein:

the injector includes a hollow pressure jacket projecting therefrom having an open front end, the opening being located at the front end of the pressure jacket, the jacket having an internal cross-section dimensioned to surround and provide pressure restraining exterior support to the body of a syringe, inserted in the jacket through the opening, between at least the rearward end of the body to the rim;

the peripheral rim of the syringe is located at the forward end thereof;

the syringe inserting step includes the step of translating the syringe rearwardly and inserting thereby the body of the syringe, from the rearward end to the rim, into the jacket; and

the rotating step includes the step of locking the forward end of the syringe to the front end of the jacket.

[13] Claim 2 of the '261 patent provides as follows:

The disposable replacement syringe of claim 1 for use with an injector having a pressure jacket extending forwardly therefrom, the jacket having a cylindrical bore therein, the opening of the injector being the hollow bore of the jacket, and wherein the internal sections are fixedly located on the inside of the jacket, wherein:

the radially extending mating sections of the locking structure comprise mating sections positioned in a plane perpendicular to the axis of the body of the syringe so as to align with the internal sections on the jacket when the syringe is inserted in the jacket and to lock the syringe to the jacket.

(Continued on following page)

L-F is applying the doctrine of claim differentiation in an attempt to broaden the asserted claims beyond their scope determined in light of the specification. *See Multiform Desiccants*, 133 F.3d at 1480. The specification does not contemplate a jacketless injector or instruct on the concept, design, or use of a jacketless injector. Thus, the Court cannot conclude simply because the term "pressure jacket" was explicitly used in dependent claims and not in the asserted claims, that the patents disclose a jacketless injector. As stated above, claim differentiation only creates a presumption that each claim has a different scope. "[C]laims that are written in different words may ultimately cover substantially the same subject matter." *Multiform Sesiccants*, 133 F.3d at 1480; *see, also, Tandon Corp. v. U.S. Int'l Trade Comm.*, 831 F.2d 1017, 1023 (Fed.Cir. 1987) ("[P]ractice has long recognized that 'claims may be multiplied . . . to define the metes and bounds of the invention in a variety of different ways'.") (quoting *Bourns, Inc. v. United States*, 537 F.2d 486, 492 (Fed.Cir. 1976)).

Accordingly, the Court concludes that the terms "syringe receiving opening" and "opening" refer to a circular width of a size to accommodate the back end of a

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Claim 19 of the '261 patent provides as follows:

> The injector of claim 18 wherein:
>
> the injector has a pressure jacket extending forwardly from the housing, the jacket having a cylindrical bore therein, the syringe receiving opening of the injector being in the bore of the jacket; and
>
> the mating sections at the opening are fixedly located on the jacket, whereby the radially extending sections of the locking structure lock the syringe to the jacket.

(Doc. No. 30, Exhs. 1, 2).

syringe. Furthermore, the Court concludes that the injector described in the asserted claims of the '669 and '261 patent requires a pressure jacket and that the syringe receiving opening/opening is located at the front of this pressure jacket.

C. "High Pressure"

Next, the Court must interpret the term "high pressure" as it is used in Claim 10 of the '669 patent, which claims "[a] method of loading a tubular replacement syringe into a ***high pressure*** power injector for injecting fluid into an animal." (Doc. No. 30, Exh. 1; '669 patent, col. 10, lines 17-18) (emphasis added). As the following analysis demonstrates, the term "high pressure" must be construed in its context as an adjective of the term "power injector." Therefore, the Court will construe the entire term "high pressure power injector"

The language of Claim 10 does not define the term "high pressure." However, when describing the syringe to be loaded into the injector, the claim does state that the syringe must be "capable of withstanding, . . . an operating pressure of at least 100 psi [pounds per square inch]." (Doc. No. 30, Exh. 1; '669 patent, col. 10, lines 32-34). Based on this language, L-F argues that the term "high pressure" means operating at pressures of ***at least*** 100 psi. (Doc. No. 164, p. 20).

While the claim language relied on by L-F may be relevant to the Court's overall analysis of the term "high pressure", it cannot, standing alone, define the term "high pressure." The claim language does not clearly delineate the pressure range to be attributed to the term "high

pressure". As a result, the Court must interpret the claim language in light of the specification and prosecution history to ascertain the meaning of "high pressure."

When discussing injection pressures, the specification for the '669 patent states that:

> For applications such as the injection of contrasting fluid for CT scanning, pressure may typically be in the range of from 25 to 300 psi, while in some angiographic injection applications the pressure may range to 1200 psi or higher.
> '669 patent, col. 12, line 24-27

(Doc. No. 30, Exh. 1). In other words, an injector operates at a pressure range of 25-300 psi for CT applications and operates at a pressure range up to 1200 psi or higher for angiographic applications. Thus, by determining which applications the injector in Claim 10 is capable of performing, the Court can infer the meaning of "high pressure power injector" as it is used in Claim 10.

The claim language does not indicate whether the injector disclosed in Claim 10 is capable of CT applications, angiographic applications, or both CT and angiographic applications. Thus, the Court must look to the specification and prosecution history for guidance on this issue. The specification for the '669 patent indicates that the injector described in the specification can be used for angiographic and/or CT applications:

> FIG. 1 is a perspective view of an angiographic CT injector embodying principles of the present invention. '669 patent, col. 5, lines 21-22

* * *

> Referring to FIG. 1, an angiographic injector 10 according to another preferred embodiment of the present invention is illustrated, configured for CT applications. '669 patent, col. 6, lines 12-14

(Doc. No. 30, Exh. 1). The question then becomes whether the injector described in Claim 10, like the injector described in the specification, is capable of both CT and angiographic application, only CT applications, or only angiographic applications.

The specification goes on to state that the fluid used in the injector "may be of relatively high pressure in the range, usually over 200 psi." (Doc. No. 30, Exh. 1; '669 patent, col. 12, lines 22-23). The implication of this statement is that pressures over 200 psi are considered high, therefore a "high pressure power injector", as in Claim 10, would be an injector that operates at pressures of 200 psi or higher, which would include both CT applications and angiographic applicaitons.

The conclusion that "high pressure power injector" refers to an injector that is capable of performing both CT and angiographic applications is also supported by the prosecution history of the '669 patent. L-F offered the following statements to the PTO Examiner during prosecution of the '669 patent:

> Claim 95[14] relates specifically to ***high pressure power injectors, as for example the injectors used in angiography, with CAT[15] equipment and the like.*** For such uses, applicants' front

[14] Claim 95 issued as claim 10 of the '669 patent.

[15] The terms CT and CAT are synonymous.

> loading injector is totally new. The front loading feature is embodied in the simple operator motion of inserting the syringe into the injector by a rearward axial motion and twisting the syringe a fraction of a turn (as for example the quarter turn of the embodiment described in the specification).

(Doc. No. 84, Exh. 3 (B) at MED 002326). (emphasis added). At first glance, it is unclear whether "with CAT equipment and the like" is a phrase modifying the term angiography or whether it is part of a series of injector applications with "angiography" being the first in the series, with "with CAT equipment" being the second in the series, and with "the like" being the third in the series. However, a reading of the full prosecution history reveals that this statement, although grammatically incorrect, involves a series of injector applications.[16] Therefore, Claim 95 related to "high pressure power injectors" such as those used in angiography and those used with CT equipment.

It should be noted that the individual independent claims of the '669 patent refer to an injector as a "high pressure power injector", a "power injector", or simply an

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[16] When discussing Claim 91 (issued as claim 1 of the '669 patent), L-F states that "claim 91 relates to the advantage of the present invention by which the efficiency of the use of a power injector, ***such as used in angiography and with CAT scanning equipment***, is enhanced." When distinguishing this "present invention" from prior art devices, L-F states that "[t]he prior art devices provided for angiography and CAT scan uses do not have this capability." From these statements, the Court infers that "used . . . with CAT scanning equipment" is the equivalent of "CAT scan uses". (Doc. No. 84, Exhibit 3 (B) at MED 002324-002325) (emphasis added).

"injector."[17] Nothing in the language of the various claims indicates whether the use of these different terms is intended to describe injectors capable of different applications. Medrad would argue that the use of these different terms indicates that the injector is intended to perform different applications. However, there is nothing in the specifications or prosecution history to support this conclusion. In fact, the prosecution history supports the opposite conclusion, that there is no difference in the terms. During patent prosecution, L-F stated the following to the PTO Examiner:

> Applicants' invention relates to relatively ***high pressure power injectors*** . . . In order to focus more clearly on the particular features of the present invention and the advantages it provides, applicants have replaced the claims with seven independent claims, each relating to a particular unique problem and unique advantageous solution provided by the invention.

(Doc. No. 84, Exhibit 3(B) at MED 002324) (emphasis added). L-F then went on to discuss the seven independent claims referred to in this excerpt, which were apparently related to "high pressure power injectors." Those claims, 91, 93, 95, 100, 101, 103, and 105, issued as independent claims 1, 6, 10, 19, 20, 22, and 24 respectively. The issued claims refer to an injector as a "power injector" (claims 1, 19, 22), a "high power pressure injector" (claims 10, 20, 24), and an "injector" (claim 6). The inference to be drawn is that the terms "power injector", "high power pressure

[17] The independent claims of the '669 patent are 1, 6, 10, 19, 20, 22, 24, 31, and 36.

injector", and "injector" all refer to the same type of injector, i.e., a "high pressure power injector." This conclusion is consistent with the principle that "[c]laims that are written in differnet words may ultimately cover substantially the same subject matter." *Multiform Desiccants*, 133 F.3d at 1480

Accordingly, based on all the intrinsic evidence, the Court concludes that the "high power pressure injector" described in Claim 10 of the '669 patent is capable of performing angiographic as well as CT applications. As such, it operates at pressures ranging from 25 psi to in excess of 1200 psi.

D. "Physical Indicia"

L-F moves the Court to construe the term "physical indicia" as it is used in the asserted claims of "the '612 patent" and the '197 patent.[18]

Each of the asserted independent claims of the '612 patent and the '197 patent includes the term "physical indicia."[19] These "physical indicia" relate to various

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[18] The asserted claims of the '612 patent are 7, 8, 10, and 11 and the asserted claims of the '197 patent are 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22, 23, 25, and 27.

[19] . . . a detector located proximate to a syringe . . . for detecting a physical indicia on said syringe related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia,
'612 patent, Claim 7,

detecting a physical indicia on a syringe . . . , said indicia being related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia . . .
'612 patent, Claim 10

(Continued on following page)

. . . a syringe having . . . physical indicia related to the distance of the plunger from an end of said syringe . . .
'197 patent, Claim 1

. . . detecting a physical indicia on a syringe installed on said injector, said indicia being related to the distance of the plunger from an end of said syringe . . .
'197 patent, Claim 4

. . . a syringe having . . . physical indicia related to the amount of fluid in the syringe . . .
'197 patent, Claim 7

. . . detecting a physical indicia on a syringe installed on said injector, said indicia being related to amount of fluid in said syringe . . .
'197 patent, Claim 10

. . . a syringe having . . . physical indicia related to the end of travel position of an injector ram coupled to the plunger when the syringe is coupled to an injector . . .
'197 patent, Claim 13

. . . detecting a physical indicia on a syringe installed on said injector, said indicia being related to the end of travel position of a ram moved by said motor when said syringe is mounted to the injector . . .
'197 patent, Claim 16

. . . a syringe having . . . physical indicia related to the range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector . . .
'197 patent, Claim 19

. . . detecting a physical indicia on a syringe installed on said injector, said indicia being related to the range of travel of a ram moved by said motor when said syringe is mounted to the injector . . .
'197 patent, Claim 22

. . . wherein the control circuit is operable obtain an offset value from physical indicia detected on the syringe . . .
'197 patent, Claim 25

. . . detecting a physical indicia on a syringe . . . , said indicia being related to the capacity of said syringe, to obtain an offset value, computing a value indicative of the location of said plunger within said syringe by applying the store offset value to the tracked location of said motor, and

(Continued on following page)

properties of a syringe such as the capacity of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, and an offset value.

L-F urges this Court to give the term "physical indicia" its ordinary and customary meaning without looking beyond the claim language. Physical is defined as "of or relating to . . . material things as opposed to things mental, moral, spiritual, or imaginary." Webster's Third New International Dictionary at 1706 (1971). Indicia is defined as "a distinctive mark that indicates or that is felt to indicate the nature or quality or existence or reality of something." *Id.* at 1150. Thus, the term "physical indicia" means a tangible marking on a syringe that relates to a specific property of the syringe. L-F proposes that these specific properties include the capacity of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, and an offset value that is related to the capacity of a syringe. (Doc. No. 164, p. 24).

Medrad does not appear to disagree that the term "physical indicia" means a tangible marking on a syringe that relates to a specific property of the syringe. Rather, Medrad is arguing that "physical indicia", as used in the '612 and '197 patents, is limited only to indicia that

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ceasing motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.
'197 patent, Claim 27
(Doc. No. 30, Exhs. 3, 4).

indicate the length of an extender element used in a syringe.[20] (Doc. No. 172, pp. 29-30).

It should be noted that the language of the asserted claims does not limit the term "physical indicia" to the use of an extender element. Rather, the claim language unambiguously states that "physical indicia" are related to capacity of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, and an offset value. *Supra*, fn. 19. Therefore, unlike the ambiguous language construed in Section III(B) ("syringe receiving opening"/requirement of a pressure jacket), the claim language relating to the term "physical indicia" is clear and unambiguous. This distinction is significant because it affects the manner in which this Court will view the rest of the intrinsic evidence, *i.e.*, the specification and the prosecution history. The Federal Circuit has recently held that:

> If the claim language is clear on its face, then our consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified. A deviation may be necessary if "a patentee [has chosen] to be his own lexicographer and use terms in manner other than their ordinary meaning." *Vitronics*, 90 F.3d at 1582, 39 USPQ2d at 1576. A deviation may also be necessary if a patentee has "relinquished [a] potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference." *Elkay Mfg.*

[20] An extender is an element in a syringe that compensates for variations in the location of the plunger in pre-filled syringes to accommodate varying syringe volumes.

> *Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979, 52 USPQ2d 1109, 1113 (Fed. Cir. 1999). If however the claim language is not clear on its face, then our consideration of the rest of the intrinsic evidence is directed to resolving, if possible, the lack of clarity.

Interactive Gift Express, 256 F.3d at 1331. Therefore, when construing the term "physical indicia", the Court will rely on the rest of the intrinsic evidence to determine only if a deviation from the clear language of the claim is specified rather than to resolve the meaning of the claim language, as it did in Section III(B).

Medrad bases its argument that "physical indicia" is limited to indicating the length of an extender on the following excerpts from the specifications of the '612 and '197 patents[21]:

> The offset value . . . may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.
> '612 patent, Abstract

> Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.
> '612 patent, col. 4, lines 2-3
> '197 patent, col. 4, lines 1-2[22]

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[21] As explained in detail in footnote 4, the '612 and '197 patents have the same specification.

[22] Medrad also cites to unasserted Claim 3 of the '612 patents which states, in pertinent part, that the injector contains a detector used for "detecting the length of the extender which is attached to said

(Continued on following page)

(Doc. No. 30, Exhs. 2, 3). Medrad argues that this language defines "physical indicia" as indicia related only to length of extender. Not surprisingly, L-F counters that this language is merely a preferred embodiment in which the physical indicia on the syringe indicates a specific property – the length of an extender.[23] (Doc. No. 182, p. 15). L-F argues that this embodiment does not preclude the use of physical indicia in relation to other properties of the syringe (*i.e.*, capacity, distance of the plunger from the end, amount of fluid, etc.).

Medrad also cites to the prosecution history of the '197 patent to support its interpretation. (Doc. No. 172, pp. 30-32). Claim 7 of the '197 patent includes the element "physical indicia related to the amount of fluid in the syringe," and claim 10 of the '197 patent includes the element of a "[physical] indicia being related to amount of fluid in said syringe." During the prosecution of the '197 patent, the PTO Examiner rejected L-F's proposed claims 7 and 10 due to failure to comply with the written description requirement of 35 U.S.C. section 112. In the Detailed Action, the PTO Examiner, in rejecting claims 22-45, explained that

> The specification, as originally filed on 28 August 1997, does not adequately support the

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plunger from physical indicia on the syringe or extender and generating an electrical signal representative of the detected length . . . " (Doc. 30, Exh. 3). In light of the law of claim differentiation discussed in section III(B), this claim language does not support Medrad's argument. Unlike the siguation in section III(B), L-F is not attempting to broaden the asserted claims beyond the scope of the claim language.

[23] The Court notes that the language in question falls under the heading "Summary of the Invention" as opposed to the later heading of "Description of the Preferred Embodiments."

> embodiments set forth in claims 22-27 wherein the syringe includes physical indicia related to the position of the plunger; claims 28-33 wherein the syringe includes physical indicia related to the amount of fluid in the syringe; claims 34-39 wherein the syringe includes physical indicia related to the end of travel position of a ram moved by the motor; and claims 40-45 wherein the syringe includes physical indicia related to the range of travel of a ram moved by the motor. The only recitation in the specification regarding the indicia on the syringe is on page 6, lines 23-26:
>
> 'Alternatively, the offset value may be automatically computed by detecting physical indicia on the syringe or extender which indicate the length of the extender.'
>
> Thus there is inadequate disclosure of such indicia being related to plunger position, fluid quantity, end of travel position of the ram, and range of travel of the ram as now claimed. The disclosure only provides support for the indicia being related to the length of the extender.

(Doc. No. 172, Exh. 10, p. 2). The PTO Examiner rejected claims 22-45 based on failure to comply with 35 U.S.C. section 112, first paragraph. (*Id.* at 3).

In response to the PTO Examiner, L-F argued that the other elements of "capacity of the syringe" and "amount of fluid in the syringe" were related to the length of the extender, and thus, those elements were supported in the specification through the references to the length of the extender:

> With respect to claims 28-33, the Examiner submits that the specification does not support physical indicia on a syringe related to the

> amount of fluid in the syringe, and does not support computing the amount of fluid in the syringe.
>
> In response, Applicant would note that a comparison of Fig. 1A to Fig. 1B clearly shows that the capacity of a syringe having an extender is less than the capacity of a syringe that does not have such an extender. Notably, the syringe shown in Fig. 1B is a 'pre-filled' syringe, thus the syringe is filled to its capacity when it is installed on the injector. Since the capacity of the syringe is directly related to the length of the extender in the syringe, it follows that the amount of fluid in the syringe is directly related to the length of the extender. Accordingly, the indicia recited at page 6, which indicates the length of the extender, also thereby indicates the amount of fluid in the syringe. Indeed, at page 4, line 4 it is stated that the extender 'reduc[es] the initial volume of the pre-filled syringe'. Accordingly, Applicant submits that the specification clearly describes a syringe having indicia related to the amount of fluid in the syringe.

(*Id.* at 12-13). L-F made similar arguments with respect to physical indicia relating to the distance of the plunger from the end of a syringe, the end of travel position of an injector ram, and the range of travel of an injector ram. (*Id.* at 10-12, 13-16). The patent was subsequently issued by the PTO without any substantive amendment by L-F of the claims or specification. (Doc. No. 174, Exh. 4, Notice of Allowance on 4/1/99, p. 139).

The Court would agree with Medrad's argument that the term "physical indicia" is limited to indicia related to the length of the extender if the preceding excerpts from L-F's response to the PTO Examiner reflected the entirety

of L-F's response. However, in the final paragraph of L-F's response, L-F stated that:

> Applicant would further note that although the supporting specific embodiment of the invention found in the specification is disclosed in the context of compensating for the presence of a plunger extender attached to the plunger, the independent claims do not necessarily require a plunger extender, but rather are directed generally to using information from indicia on a syringe to compensate for syringes having differing initial plunger positions, differing initial amounts of fluid, differing end-of-travel positions or ranges of travel for the ram.

(*Id.* at 16). Thus, L-F unequivocally stated to the PTO Examiner that the asserted claims of the '197 patent were not limited to indicia relating to the length of an extender.

In order to narrow unambiguous claim language based on the prosecution history, an accused infringer must "demonstrate that the patentee 'defined' the claim as 'excluding' a broader interpretation 'with reasonable clarity and deliberateness.'" *Pall Corporation v. PTI Technologies, Inc.*, 259 F.3d 1383, 1392-93 (Fed. Cir. 2001) (quoting *Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1294-95 (Fed.Cir. 2000)). Based on the final paragraph of L-F's response, the Court cannot conclude that L-F limited the asserted claims to "physical indicia" only related to the length of an extender. L-F clearly viewed "physical indicia" as encompassing other syringe characteristics besides the length of the extender.

Thus, the Court construes the term "physical indicia" as a tangible mark on a syringe relating to various properties of the syringe. The properties may include the capacity

of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, or an offset value.

Medrad argues that in the event the Court accepts L-F's construction of the term "physical indicia", the '612 and '197 patents are invalid pursuant to 35 U.S.C. § 112 for lack of enablement and failure to provide an adequate written description. (Doc. No. 172, pp. 32-33). This argument will be addressed in section VII(A).

E. "Motor" and "Tracks the Location of Said Motor"[24]

L-F requests that the Court interpret the terms "motor" and "tracks the location of said motor" as they are used in the '612 and '197 patents. Each of the asserted independent claims of the '612 and '197 patents recites that the injector has a motor which advances and retracts a plunger and that the device includes a control circuit which causes the motor to move and tracks the location of the motor while moving the motor.

L-F asserts that "motor" actually means the "drive mechanism" and "tracks the location of said motor" means "tracks the location of the drive mechanism." (Doc. No. 164, pp. 26-27). Medrad, relying strictly on dictionary definitions, argues that "motor" means a machine that

[24] The Court reviewed L-F's Supplementation in Reply (Doc. No. 220) relating to this issue, Medrad's Motion to Strike L-F's Supplementation (Doc. No. 224), and L-F's memorandum in opposition (Doc. No. 235). These filings relate to extrinsic evidence not considered by the Court when construing the claim terms.

imparts motion and that "tracks the location of said motor" means that the motor is moving to another location within the injector and that this movement is being tracked. (Doc. No. 172, pp. 33-34). The Court finds both L-F's and Medrad's arguments illogical and unpersuasive.

The terms "motor" and "tracks the location of said motor" are not defined by any of the asserted claims in the '612 and '197 patents. Therefore, the claims must be read in light of the specification to define the terms. *See Interactive Gift Express*, 256 F.3d at 1331.

The Court believes the following excerpt from the specification sufficiently defines the terms in question.

> The motor 98 is coupled to a gear box which translates rotary motion of the motor to linear translation of the plunger . . . The rotation of the motor is detected by optical encoder 166 . . . Encoder 166 sends electrical pulses to circuit board 160, which relays them to PowerPC 50, allowing CPU 52 on the PowerPC to monitor movement of the motor.
> '612 patent, col. 10, lines 50-62
> '197 patent, col. 10, lines 48-60

(Doc. No. 30, Exhs. 3, 4). In other words, the "motor" is a mechanism that rotates and this rotation causes gears in the gear box to move which ultimately results in the linear movement of the plunger. "Track the location of said motor" refers to the monitoring of the rotation of the motor.[25]

[25] In Plaintiff Liebel-Flarsheim Company's Opposition to Medrad's Motion for Partial Summary Judgment of Invalidity and Non-Infringement of the Asserted Claims of U.S. patent Nos. 5,662,612 and

(Continued on following page)

L-F's proposed interpretation equates "motor" with the "drive mechanism of the plunger". However, the term "motor" is shown in the specifications and used in the claims as a distinct element. "Motor" is assigned reference number 98 and is depicted in Figure 5 of both patents, where the motor is different and distinct from the "gear box" (Ref. No. 164), the "optical encoder" (Ref. No. 166), the "plunger" (Ref. No. 12), the "linear pot" (Ref. No. 168), the "main circuit board" (No. 160), and other elements. (Doc. No. 30, Exhs. 3, 4). It appears that the "drive mechanism" includes parts in addition to the motor such as the gearbox, the ram, and all of the component parts that work to drive the plunger. Therefore, the motor cannot be the equivalent of the drive mechanism of the plunger.

Medrad's proposed interpretation, that the motor is moving from location to location, ignores the specification which clearly indicates that the motor is stationary. Furthermore, Medrad's proposed interpretation would exclude the preferred embodiment disclosed in the '612 and '197 patents, which describes a motor that is stationary. *See Vitronics*, 90 F.3d at 1583; *Burke, Inc. v. Brundo Independent Living Aids, Inc.*, 183 F.3d 1334, 1341 (Fed.Cir. 1999).

In light of the clear and unambiguous language of the specification, the Court finds that its construction of the terms "motor" and "tracking the movement of the motor" is

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5,928,197 (Doc. 174), L-F, in its argument regarding the construction of the terms "motor" and "tracks location of said motor", presented an argument identical to the Court's present analysis of these terms. It is unclear why L-F presented a completely different, and in the Court's opinion incorrect, argument in its summary judgment motion for claim construction.

the more logical construction. Therefore, the Court construes the term "motor" as a stationary mechanism that rotates causing the movement of the gears in the gearbox and the term "tracking the movement of the motor" as the monitoring of the rotation of the motor.

IV. DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY FOR LACK OF ENABLEMENT OF THE ASSERTED CLAIMS OF THE '669 AND '261 PATENTS (DOC. 168)

Medrad failed this motion for partial summary judgment. (Doc. No. 168). L-F filed a Response (Doc. No. 175) to which Medrad filed a Reply (Doc. No. 187).

Based on the Court's construction that a pressure jacket is a required element of the asserted claims of the '669 and '261 patents (Section III(B)), the Court declares **MOOT** Defendant's Motion for Partial Summary Judgment of Invalidity for Lack of Enablement of the Asserted Claims of the '669 and '261 Patents (Doc. No. 168).

V. DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY AND NON-INFRINGEMENT OF THE ASSERTED CLAIMS OF THE '669 AND '261 PATENTS (DOC. 57)

Medrad filed this motion for partial summary judgment. (Doc. No. 57). L-F filed a Response (Doc. No. 84) to which Medrad filed a Reply (Doc. No. 99).[26] [27]

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[26] The Court also reviewed Medrad's Motion to File a Sur-Reply (Doc. No. 190) and L-F's memorandum in opposition (Doc. No. 196).

[27] L-F also filed a motion to file a sur-reply (Doc. No. 104). Medrad filed a memorandum in opposition (Doc. No. 113) to which L-F filed a

(Continued on following page)

A. Brief Background

Medrad seeks summary judgment arguing that if the asserted claims of the '669 and '261 patents are construed as not requiring a pressure jacket, the patents are invalid for failure to comply with the written description requirements of 35 U.S.C. § 112, ¶ 1. In the alternative, Medrad argues that if the asserted claims are construed as requiring a pressure jacket, it is entitled to summary judgment for non-infringement of the '669 and '261 patents because the accused products do not include a pressure jacket.

Based on the Court's construction that the asserted claims require a pressure jacket (Section III(B)), the portion of Medrad's motion for summary judgement based on invalidity is **MOOT**. The Court now addresses Medrad's non-infringement portion of its motion.

B. Non-Infringement of the '669 and '261 Patents

Infringement is the unlicenced making, using, or selling of a patentee's claimed invention. 35 U.S.C.A. § 271(a). Literal infringement occurs when the accused product is precisely described in a patent claim. *SRI Int'l*, 775 F.2d at 1123. Under the doctrine of equivalents, infringement occurs when the accused product "performs substantially the same overall function or work, in substantially the same way, to obtain substantially the same

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Reply (Doc. No. 120). L-F did not file a sure reply but instead filed a supplemental memorandum in opposition (Doc. No. 195). Medrad filed a Response (Doc. No. 199) to which L-F filed a Reply (Doc. No. 203). These filings involve findings by the European Patent Office. This Court did not consider these findings when ruling on this matter.

overall result as the claimed invention." *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed.Cir. 1987) (en banc), *cert. denied*, 485 U.S. 961, 485 U.S. 1009 (1988).

To determine infringement, the court must apply a two-step analytic procedure. *Wang Labs.*, 197 F.3d 1377, 1380-81 (Fed.Cir. 1999) (citations omitted); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1476 (Fed.Cir. 1998) (citation omitted). First, the court must construe the scope and meaning of the patent claims asserted, which are questions of law. *Id.* Then, the court must apply those claims to the allegedly infringing device or process, which is a question of fact. *Id.*

To establish literal infringement, every limitation set forth in a claim must be found in the accused product, exactly. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed.Cir. 1999), *cert. denied*, 529 U.S. 1066 (2000) (quoting *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed.Cir. 1998)); *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed.Cir. 1995), *cert. denied*, 514 U.S. 987 (1995). As a matter of law, there is no literal infringement if any claim limitation is absent from the accused device. *Elkay Mfg. Co.*, 192 F.3d at 980.

Because "infringement is itself a fact issue, a district court must approach a motion for summary judgment of infringement or non-infringement with a care proportioned to the likelihood of its being inappropriate." *SRI Int'l*, 775 F.2d at 1116 (citing *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1573 (Fed.Cir. 1985)); *Palumbo v. Don-Joy Co.*, 762 F.2d 969, 974 (Fed.Cir. 1985). "[A] trial often establishes facts and inferences not gleanable from papers submitted pre-trial." *SRI Int'l*, 775 F.2d at 1116.

In section III(B), this Court held that the injector described in the asserted claims of the '669 and '261 patents required a pressure jacket. It is undisputed that the accused injectors do not include a pressure jacket. Therefore, because a claim limitation, a pressure jacket, is absent from the accused products, there is no literal infringement of the '669 and '261 patents as a matter of law. *Mas-Hamilton Group*, 156 F.3d at 1211 (Fed.Cir. 1998) ("If even one limitation is missing or not met as claimed, there is no literal infringement.") (citations omitted).

Furthermore, it does not appear, nor has L-F argued, that the accused products include the equivalent of a pressure jacket. Therefore, there is no infringement under the doctrine of equivalents. *See Mas-Hamilton Group*, 156 F.3d at 1215-16 (explaining that when an accused device is missing the equivalent of a claim limitation there is no infringement under the doctrine of equivalents). *See also, Anderson*, 477 U.S. at 248 (The non-moving party "'may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial.'" (citations omitted)).

Thus, the Court concludes that there is no genuine issue as to any material fact with respect to non-infringement of the '669 and '261 patents and that Medrad is entitled to judgment as a matter of law.

Thus, the Court **GRANTS**, with respect to non-infringement, Defendant's Motion for Partial Summary Judgment of Invalidity and Non-infringement of the Asserted Claims of the '669 and '261 Patents (Doc. 57) and declares the motion **MOOT** with respect to invalidity.

VI. DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE '612 AND '197 PATENTS BECAUSE DEFENDANT PRACTICES ITS OWN PATENT WHICH IS PRIOR ART TO THE ASSERTED PATENTS (DOC. 162)

Medrad filed this motion for partial summary judgment. (Doc. No. 162). L-F filed a Response (Doc. No. 163) to which Medrad filed a Reply (Doc. No. 170).[28]

A. Brief Background

Medrad seeks summary judgment on L-F's claims that Medrad infringed claims 7, 8, 10, and 11 of the '612 patent and claims, 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22, 23, 25, and 27 of the '197 patent.

The '612 patent issued on September 2, 1997 from an application filed June 26, 1995, and the '197 patent issued on July 27, 1999 from an application filed August 28, 1997. (Doc. No. 162, Exhs. 1, 2). The claims of the '197 and '612 patents recite specific uses of encoding information on a syringe which the patents refer to as "physical indicia."[29]

Prior to the filing of L-F's above-mentioned applications, Medrad, on August 17, 1992, filed an application which resulted in U.S. Patent No. 5,383,858 ("the '858 patent"). (Doc. No. 162, Ex. 3). The '858 patent, entitled "Front-Loading Medical Injector and Syringe For Use Therewith," was issued on January 24, 1995. Among other

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[28] The Court also reviewed L-F's Motion to File a Sur-Reply (Doc. No. 178), Medrad's memorandum in opposition (Doc. No. 180), and L-F's reply (Doc. No. 188).

[29] *Supra*, fn. 19.

things, the '858 patent discloses a method and device for syringe encoding (collectively "syringe encoding").[30]

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[30] The '858 patent provides as follows:

> With further reference to FIG. 2, a system 67 for transmitting syringe information from the syringe 22 to an injector controller 68, illustrated in phantom lines in FIG. 1, while attaching the syringe to the injector housing front wall mounting assembly 23, also is provided. In this instance, the system 67 comprises an encoding device 70, such as a bar code having spaced bars 70b and located on the syringe 22, and a sensor 72 located on the injector 27, as for example, in a second one of the connector assembly retaining flanges 23f. Then, as the syringe 22 is rotated into its mounted position, the sensor 72 reads the encoding device 70 and forwards associated signals to the injector controller 68, which then interprets the signals and modifies the function of the injector apparatus 20 accordingly. Examples of the information which could be encoded on the encoding device 70 include dimensions of the syringe 22, content of the syringe in the case of a pre-filled syringe, manufacturing information such as lot numbers, dates and tool cavity number, recommended contrast media flow rates and pressures, and loading/injection sequences. As an alternative to the encoding device 70 being a bar code with spaced bars 70b, the encoding device also could include raised surfaces 70s corresponding to the spaced bars, which then would be read by a suitable injector sensor 72 in a similar manner, as the syringe 22 is mounted on the injector housing front wall 24. In addition to the encoding device 70, one may also use mechanically readable devices, e.g., a slot, hole, or projection on the syringe 22 or plunger 38 to register against a switch on the mounting assembly 23, or alternatively an optically readable device, e.g. characters, dots and other geometric shapes, that will send information concerning the type of syringe used to the intelligent circuits of the injector. '858 patent, col. 6, lines 31-65

(Doc. No. 162, Exh. 3).

B. Discussion

On summary judgment, Medrad argues that the accused products cannot, as a matter of law, infringe the '612 and '197 patents because Medrad practices its own prior art patent, the '858 patent. (Doc. No. 162, p. 10). Medrad contends that the accused products include the syringe encoding covered by the '858 patent. (Doc. No. 162, p. 2). Medrad argues further that because the '858 patent was issued in 1995, it constitutes prior art to the '612 and '197 patents, which were issued in 1997 and 1999, respectively. (Doc. No. 162, p. 3). Therefore, Medrad contends that it is practicing the prior art. If Medrad's conclusion is correct, the accused products cannot infringe the asserted patents literally or under the doctrine of equivalents. *See Fiskers, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1323 (Fed.Cir. 2000), *cert. denied*, 121 S.Ct. 1603 (2001) (it is an affirmative defense of an alleged infringer to establish that it is practicing the prior art).

To determine whether Medrad is practicing the prior art the Court must determine (1) whether the '858 patent is prior art to the '612 and '197 patents and (2) whether the accused products are covered by the '858 patent with respect to syringe encoding.

The parties appear to agree that the '858 patent is prior art to the '612 and '197 patents. Therefore, the next issue for the Court's consideration is whether the accused products are covered by the '858 patent, in particular with respect to the patent's syringe encoding disclosures. Medrad contends that the accused products include the syringe encoding disclosed by the '858 patent. In support of its contention, Medrad relies on the Second Declaration of Joseph B. Havrilla, the Senior Vice President of New

Project Development for Medrad. (Doc. No. 162, Exh. 6). In his declaration, Havrilla states that:

> 3. Medrad's Envision CT™ and Medrad Vistron CT® injectors, and the syringes for use with these injectors, incorporate and practice inventions described in Medrad U.S. Patent No. 5,383,858 ("the '858 patent") filed August 17, 1992 and issued January 24, 1995.
>
> 4. In particular, Medrad's Envision CT™ and Medrad Vistron CT® injectors, and the syringes for use with these injectors, feature a syringe encoding apparatus and method as disclosed in column 6, lines 31-65 of the Medrad '858 patent. The same disclosure of syringe encoding appears in two other Medrad patents, U.S. Patent Nos. 5,997,502 ("the '502 patent") and 6,090,064 ("the '064 patent"), both of which have an August 17, 1992 effective filing date and both of which also explicitly claim syringe encoding. Medrad's Envision CT™ and Medrad Vistron CT® Injectors, in particular the syringe encoding aspects of these injectors, operate as disclosed in Medrad's '858 patent and as claimed in Medrad's '502 and '064 patents.

(Doc. No. 162, Exh. 6, ¶¶ 3, 4). Medrad also cites to statements made by two of L-F's own experts, Dennis A. Guenther and Arthur J. Helmicki, in support of its argument.[31] With respect to the statements of Guenther and

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[31] Medrad cited to the January 31, 2001 *Rebuttal report of Dennis A. Guenther, Ph.D., P.E. Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure* in Civil Action C 1-98-858, (Doc. 162, Exh. 8) and to the Report of Arthur J. Helmicki, Ph.D., Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, (Doc. 162, Exh 9 (page 1 of Exh. B and page 1 of Exh. C)).

Helmicki, the Court concludes that they are not related to the issue of whether the accused products include the syringe encoding disclosed in the '858 patent. Therefore, the only credible evidence Medrad has presented that the accused products are covered by the '858 patent with respect to syringe encoding is the declaration of Havrilla.

L-F does not take a position on whether the accused products practice the prior art of the '858 patent with respect to syringe encoding. Rather, L-F argues that this issue is irrelevant because even if the accused products practice the prior art of the '858 patent, they ***also*** practice the subject matter of the claims of the '612 and '197 patents, which, L-F contends, are improvement patents of the '858 patent.[32] (Doc. No. 163, pp. 8-10). As L-F accurately states, when a patentee claims an improvement over a prior invention, other parties may practice variations of that prior invention, as long as the variations are not the same as, or an equivalent of, the improvement claimed by the patentee. *See Thomas & Betts Corp. v. Litton Systems, Inc.*, 720 F.2d 1572, 1580 (Fed.Cir. 1983) (citing *Sealed Air Corp. v. U.S. International Trade Comm'n*, 645 F.2d 976, 984-85 (C.C.P.A. 1981).

L-F argues that while the '858 patent discusses syringe encoding, it only refers to syringe encoding applications not claimed in the '612 and '197 patents. According to L-F, the syringe encoding disclosed in the '858 patent identifies:

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[32] Medrad has not disputed L-F's argument that the '612 and '197 patents are improvement patents of the '858 patent.

- dimensions of the syringe
- content of the syringe in the case of a pre-filled syringe
- manufacturing information such as lot numbers, dates and tool cavity number
- recommended contrast media flow rates and pressures
- loading/injections sequences

(Doc. No. 163, p. 6 (citing '858 patent, col. 6, lines 45-51)). On the other hand, L-F points out that the syringe encoding of the '612 and '197 identifies:

- capacity of the syringe
- distance of the plunger from an end of the syringe when the syringe is initially installed on the injector
- amount of fluid in the syringe
- end of travel position of an injector ram coupled to the plunger when the syringe is coupled to the an injector
- range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector

(Doc. No. 163, pp. 4-5 (citing Exh. 1, Helmicki Affidavit ¶ 7)).[33] Further, according to L-F, the '858 patent fails to address the use of syringes that have "different end-of-travel

[33] In its reply (Doc. No. 170), Medrad asks this Court to strike Helmicki's declaration as being not credible. The Court finds Medrad's argument on this issue unpersuasive and declines to strike Helmicki's declaration.

positions, capacities, or different amounts of fluid or plunger-end-of-syringe distances." (Doc. No. 163, p. 7). Thus, L-F argues that the '858 patent "does not disclose the uses for indicia that are recited in the '612 and '197 patent claims." (Doc. No. 167, p 8). L-F argues that the accused products include syringe encoding that identifies the information contained in the '612 and '197 patents. (Doc. No. 167, p 10).

Medrad, relying on its claim construction argument that the term "physical indicia" is only related to the length of the extender, does not address L-F's argument that the accused products include syringe encoding that identifies other information besides the length of an extender. In section III(D), this Court rejected Medrad's proposed construction. Therefore, by relying exclusively on its proposed claim construction, which the Court had concluded is incorrect, Medrad has failed to present any factual evidence to dispute L-F's argument that the accused products include syringe encoding that identifies the information contained in the '612 and '197 patents.

However, the Court recognizes the difficulties faced by the parties due to the sequencing of motions in this matter. Therefore, the Court invites the parties to rebrief this argument in light of the Court's construction of the term "physical indicia". ***However, neither party should revisit the claim construction issue in any such briefings***. Briefings should be confined to the issue of infringement in light of this Court's construction of the term "physical indicia" in section III(D). Defendant Medrad's revised motion is due on November 19, 2001, Plaintiff L-F's response is due on December 10, 2001, and Defendant Medrad's reply is due on December 31, 2001.

Accordingly, the Court **RESERVES JUDGMENT** on Medrad's Motion for Partial Summary Judgment of Non-infringement of the '612 and '197 Patents Because Defendant Practices its Own Patent Which Is Prior Art to the Asserted Patents (Doc. 162).

VII. DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY OF THE ASSERTED CLAIMS OF THE '612 AND '197 PATENTS (DOC. 167)

Defendant has filed a second motion for partial summary judgment of non-infringement and invalidity of the asserted claims of the '612 and the '197 patent. (Doc. No. 167). Defendant requested that the Court hear oral argument on this motion. Plaintiff has filed a Memorandum in Opposition (Doc. No. 174) to which Defendant has filed a Reply (Doc. No. 184).

In its motion for summary judgment, Medrad argues that the accused devices do not infringe the '612 and '197 patents because the accused devices lack at least two elements of the asserted claims, a moving motor and physical indicia indicating the length of an extender. Medrad also argues that the '612 and '197 patents are invalid because the specifications of both asserted patents fail to satisfy the written description and enablement requirements of 35 U.S.C. § 112. The Court will address Medrad's invalidity argument first.

A. Invalidity of the '612 and 197 Patents

Medrad contends that the '612 and '197 patents are invalid for failure to comply with the written description

and enablement requirements provided in 35 U.S.C. § 112, ¶ 1. That paragraph provides, in pertinent part, as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

35 U.S.C. § 112, ¶ 1. This paragraph requires both a written description of the specific subject matter claimed and that the description enable one skilled in the art to make and use the claimed invention. *Rohm and Haas Co. v. Mobil Oil Corp.*, 718 F.Supp. 274, 287 (D. Del. 1989), *aff'd*, 895 F.2d 1421 (Fed.Cir. 1990); *see In re Wilder*, 736 F.2d 1516, 1520 (Fed.Cir. 1984), *cert. denied*, *Wilder v. Mossinghoff*, 469 U.S. 1209 (1985) (citations omitted).

B. Written Description

The written description provision requires that the specification of the patent describe the inventions claimed in the patent. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346 (Fed.Cir. 2000); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed.Cir. 1998). The written description must clearly allow those of ordinary skill in the art to recognize that the applicant invented what is claimed. *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996) (quoting *In re Gosteli*, 872 F.2d 1008, 1012, (Fed.Cir. 1989) (citation omitted)). "The adequate written description requirement . . . serves 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how

the specification accomplishes this is not material.'" *In re Alton*, 76 F.3d at 1172 (quoting *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976)).

A party arguing that a patent is invalid due to failure to comply with the written description requirement of § 112 carries a heavy burden. Every patent is presumed valid. *National Recovery Technologies, Inc. v. Magnetic Separation Recovery Systems, Inc.*, 166 F.3d 1190, 1195 (Fed.Cir. 1999); *Texas Instruments Inc. v. United States Int'l Trade Comm'n*, 988 F.2d, 1165, 1177 (Fed.Cir. 1993). This presumption of validity includes a presumption that the patent complies with 35 U.S.C. § 112. *National Recovery Technologies*, 166 F.3d at 1195. Thus, a party challenging the validity of a patent bears the burden of establishing invalidity by clear and convincing evidence. *Texas Instruments Inc.*, 988 F.2d at 1177; *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1575 (Fed.Cir. 1984) (stating that the burden of persuasion always remains on the party asserting invalidity); *see also National Recovery Technologies*, 166 F.3d at 1195 (quoting *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed.Cir. 1990), *cert. denied*, 498 U.S. 920 (1990)). Whether a specification complies with the written description requirement of §112 is a question of fact.

Suntiger, Inc. v. Scientific Research Funding Group, 189 F.3d 1327, 1334 (Fed. Cir. 1999); *Gentry Gallery*, 134 F.3d at 1479.

Medrad, relying on the conclusions of its experts, argues that the single phrase referring to "physical

indicia" in the specifications of the '612 and '197 patents[34] fails to convey with reasonable clarity that the inventor had possession of the claimed subject matter as of the filing date of the applications for these patents.[35] (*See also*, Doc. No. 167, Exh. 10).

In response, L-F argues that the issue of sufficiency of the written description of the '612 and '197 patents was specifically dealt with by the PTO Examiner during prosecution of the '197 patent. As discussed in great detail

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[34] The phrase referred to by Medrad is "physical indicia on the syringe or extender which indicate the length of the extender." ('669 patent, Abstract, Col. 4, lines 1-3 and '197 patent, col. 3, lines 67-69).

[35] In his declaration, Robert Sturges states:

> 12. Based on lack of disclosure by L-F, the '612 patent would not teach or enable a typical or ordinary syringe or injector designer to construct or design a syringe with "physical indicia" other than, at best, "physical indicia" on the extender related to the length of the extender. The '612 patent contains no description or drawings that teach or even disclose "physical indicia" that are related to syringe capacity or other parameters.

(Doc. No. 167, Exh. 6, ¶ 12).

In his declaration, Rudy Kranys states:

> 23. I have also reviewed L-F's U.S. Patent No. 5,662,612 ("'612 patent") and L-F U.S. Patent No. 5,928,197 ("'197 patent"). Based on my review of '612 and '197 patents, the prosecution histories of the '612 and '197 patents, and the prosecution history of the related abandoned, parent U.S. Patent Application Serial No. 157,823, the L-F '612 and '197 patents only suggest to me, as one highly knowledgeable with respect to medical injectors, an injector and a pre-filled syringe system in which the injector has a detector to identify the length of the extender used with the syringe based on what is identified as "physical indicia" located on the syringe or extender that is used with the syringe.

(Doc. No. 167, Exh. 7, ¶ 23).

in section III(D), the PTO Examiner initially rejected the '197 patent for failure to comply with the written description requirement. After L-F provided a response addressing the PTO Examiner's concerns, the patent was issued with no substantive amendment of the claims or specification. (Doc. No. 174, Exh. 4, Notice of Allowance on 4/1/99, p. 139). Additionally, L-F presents the affidavit of its own expert, Arthur Helmicki, who concludes that the specification of the '612 and '197 patents is sufficient.[36]

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[36] In his affidavit, Helmicki states:

> 21. In his expert report in this matter, Medrad's expert Dr. Sturges, states that he expects" ". . . to testify, based on a lack of L-F's disclosure, that the '612 patent would not teach or enable a typical or ordinary syringe or injector designer to construct or design a syringe with 'physical indicia' other than at best 'physical indicia' on the extender related to the extender position." I disagree. It is my belief that the typical or ordinary person charged with designing control systems for an injector, would be readily able to design and construct a syringe with physical indicia and a sensor for reading those indicia, without regard to whether the indicia are on an extender or relate to properties of an extender.
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> 22. First, as quoted above from his report, Dr. Sturges accepts that the content of the '612 patent would enable a typical syringe/injector designer " . . . to construct or design a syringe with 'physical indicia' . . . on the extender related to the extender position." I agree with this statement. Moreover, I would submit that a designer of ordinary skill in the art, having taken this step, would clearly be able to realize this concept in other ways, to include "physical indicia" on the syringe, as is suggested in the '612 an '197 patents. Further, it is my opinion that a designer of ordinary skill in the art, armed with the contents of the '612 and '197 patents, would be able to carry out this activity in a straightforward manner.
>
> 23. Second, the point at issue here is the design of a device capable not only of automatically detecting "physical indicia" on the syringe but also using this information in order to achieve various automatic control objectives (e.g., remaining volume determination, end of travel shut-off, etc.). With regard to the use

(Continued on following page)

Taking into account Medrad's burden on validity, establishing invalidity by clear and convincing evidence, compounded by the fact that the Court must approach summary judgment with extreme caution, the Court finds that, in light of the prosecution history of the '197 patent and the conclusion of L-F's expert,, there are genuine issues of material fact that preclude summary judgment on the issue of invalidity based on failure to comply with the written description requirement of 35 U.S.C. § 112¶ 1.

2. Enablement

Medrad also contends that the asserted patents fail to satisfy the enablement requirement of 35 U.S.C. § 112, ¶ 1. The enablement requirement of § 112 demands "that the patent specification enable 'those skilled in the art to make and use the full scope of the claimed invention without undue experimentation.'" *National Recovery*

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of information about a syringe (however obtained) in performing automatic control, I do not see how the '612 and '197 patents can be faulted for a lack of disclosure. The '612 and '197 patents contain a number of figures (Figures 3-5) together with supporting and detailed description in the specification of the operation of such a system from a block diagram standpoint. This description even includes details of the circuitry necessary for carrying out the design. Moreover, the specification provides a detailed set of flow diagrams (Figure 7) together with associated text description outlining the exact algorithms by which automatic control of the device should be operated. Finally, the '612 and '197 patents have associated with them a microfiche appendix containing the software code needed to run an injector performing automatic control. One could hardly ask for more disclosure. In fact, I would submit that someone of less than ordinary skill in the art, when presented with such a roadmap, would be able to duplicate a device with this functionality.

(Doc. No. 174, Exh. 5, ¶¶ 21-23).

Technologies, 166 F.3d at 1195 (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed.Cir. 1997), *cert denied*, 522 U.S. 963 (1997)) (internal quotation marks and citations omitted). The scope of the claims must be equal to or less than the scope of the enablement, which is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation. *National Recovery Technologies*, 166 F.3d at 1196.

Whether a specification satisfies the enablement requirement of § 112 is a "' . . . conclusion of law and must be supported by facts proved by clear and convincing evidence . . . '" *National Recovery Technologies*, 166 F.3d at 1195 (quoting *Northern Telecom*, 908 F.2d at 941). "While enablement is ultimately a question of law . . . , it is based on underlying factual findings . . . " *Bruning v. Hirose*, 161 F.3d 681, 686 (Fed.Cir. 1998).

As with the written description requirement, a court, when reviewing for enablement, must keep in mind that every patent is presumed valid and the a party challenging its validity bears the burden of establishing invalidity by clear and convincing evidence. *See National Recovery Technologies*, 166 F.3d at 1195; *Texas Instruments*, 988 F.2d at 1177; *ACS Hospital Systems*, 732 F.2d at 1575.

The extent of experimentation required to enable a patent is a key question when analyzing a patent to determine if it meets the requirements of § 112. The Federal Circuit has established the following factors which a court may consider in determining whether a disclosure would require undue experimentation for enablement purposes:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. A court need not review all of the factors. *Id.* The facts of the case determine which factors are relevant. *Id.*

In support of its argument that the specification of the '612 and '197 patents does not meet the enablement requirement of § 112, Medrad relies on the conclusions of its experts, Robert Sturges and Rudy Kranys,[37] that

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[37] In his declaration, Sturges states:

> 12. Based on lack of disclosure by L-F, the '612 patent would not teach or enable a typical or ordinary syringe or injector designer to construct or design a syringe with "physical indicia" other than, at best, "physical indicia" on the extender related to the length of the extender. The '612 patent contains no description or drawings that teach or even disclose "physical indicia" that are related to syringe capacity or other parameters.
>
> * * *
>
> 16. Based on L-F's lack of disclosure, the '197 patent would not teach or enable a typical or ordinary syringe or injector designer to construct or design a syringe with 'physical indicia' other than, at best, 'physical indicia' on the extender related to the length of the extender.

(Doc. 167, Exh. 6, ¶¶ 12, 16).

In his declaration, Kranys states:

> 24. As one highly knowledgeable with respect to medical injectors, I find no teachings in the '612 and '197 patents that would have enabled me to construct an injector and pre-filled or empty syringe system in which the injector uses a detector to detect 'physical indicia' located on the syringe (used with the extender)

(Continued on following page)

the specification would not enable one skilled in the art of medical injectors to design or construct an injector system in which the injector uses physical indicia located on the syringe to determine properties of the syringe other than the length of an extender.

In its response, L-F fails to address Medrad's lack of enablement argument. Despite this failure, L-F has presented evidence in response to Medrad's written description argument that is relevant to Medrad's lack of enablement argument. As with the written description, the issue of enablement of the '612 and '197 patents was raised by the PTO Examiner during prosecution of the '197 patent. After L-F addressed the PTO Examiner's concerns, the patent was issued with no substantive amendment of the claims or specification. (Doc. No. 174, Exh. 4, Notice of Allowance on 4/1/99, p. 139). In addition, L-F's expert, Arthur Helmicki, addressed the issue of enablement in his affidavit and concluded that the specification of the '612 and '197 patent would enable one skilled in the art to create and design an injector system that detected "physical indicia" on a syringe that indicated various properties of the syringe. *Supra*, fn. 36.

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or the extender (that is to be used with the syringe) to identify the length of the extender.

* * *

25. Additionally, I find no teachings in the '612 or '197 patents that would have enabled me to construct an injector and syringe system in which the injector uses a detector to detect "physical indicia" located on the syringe to identify the capacity of the syringe or any other parameter.

(Doc. No. 167, Exh. 7, ¶¶ 24, 25).

As discussed above, the extent of experimentation required to enable a patent is a key issue to be considered by the court when making a determination regarding enablement. Medrad has utterly failed to present any evidence related to this issue. Rather, Medrad has simply presented the conclusory statements of its experts that the specification is not enabling without any factual support. This "evidence" is not sufficient to overcome Medrad's burden of proving lack of enablement by clear and convincing evidence.[38] *In re Brandstadter*, 484 F.2d 1395, 1405-06 (C.C.P.A. 1973) (experts' conclusory statements not sufficient for enablement when no factual support provided to support conclusions). Thus, the Court finds that summary judgment is inappropriate with respect to the issue of invalidity of the '612 and '197 patents based upon lack of enablement.

B. Infringement

In section V(B) of this Order, the Court articulated the law on infringement. Rather than repeat verbatim that summary of the relevant law, the Court refers the parties to that section.

In its motion for summary judgment, Medrad argues that the accused products do not infringe the '612 and '197 patents because the accused products do not use an extender, and thus do not have physical indicia which indicate the length of the extender.

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[38] L-F's evidence on this issue is only slightly more persuasive than Medrad's evidence. However, Medrad, not L-F, has the burden of proof with respect to this issue.

Medrad's argument is based on the assumption that the construction of the claim term "physical indicia" relates exclusively to the "length of the extender." As stated in section III(D), the Court does not adopt this construction of "physical indicia". Therefore, Medrad's argument in this summary judgment motion is irrelevant in light of the Court's construction of the claims.

The Court recognizes the difficulties faced by the parties due to the sequencing of motions in this matter. Therefore, the Court invites the parties to rebrief this argument in light of the Court's construction of the term "physical indicia". ***However, neither party should revisit the claim construction issue in any such briefings.*** Briefings should be confined to the issue of infringement in light of this Court's construction of the term "physical indicia" in section III(D). Defendant Medrad's revised motion is due on November 19, 2001, Plaintiff L-F's response is due on December 10, 2001, and Defendant Medrad's reply is due on December 31, 2001.

In its motion for summary judgment, Medrad also argues that the accused products do not infringe the '612 and '197 patents because the accused products do not have a "motor that moves" and the accused products do not "track the location of said motor."

Medrad's argument is based on its faulty construction of the term "motor" and "tracks location of said motor." As stated in section III(E), the Court does not adopt Medrad's construction of the terms "motor" and "tracks location of said motor." Therefore, Medrad's argument in this summary judgment motion is irrelevant in light of the Court's construction of the claims.

Again, the Court recognizes the difficulties faced by the parties due to the sequencing of motions in this matter. Therefore, the Court invites the parties to rebrief this argument in light of the Court's construction of the terms "motor" and "tracks location of said motor." ***However, neither party should revisit claim construction issues in any such briefings.*** Briefings should be confined to the issue of infringement in light of this Court's construction of the term "motor" and "tracks location of said motor" in section III(E). Defendant Medrad's revised motion is due on November 19, 2001, Plaintiff L-F's response is due on December 10, 2001, and Defendant Medrad's reply is due on December 31, 2001.

Thus, the Court **DENIES**, Defendant's Motion for Partial Summary Judgment of Non-infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. 167), with respect to invalidity. The Court **RESERVES JUDGMENT** on Medrad's motion with respect to infringement.

VIII. PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON COUNTS I-IX OF THE FOURTH AMENDED COMPLAINT (DOC. 169)

Plaintiff filed this motion seeking summary judgment of infringement on specified claims disclosed in the '669 patent, the '261 patent, the '612 patent, and the '197 patent. (Doc. No. 169). Defendant filed a response (Doc. No. 176) to which Plaintiff filed a reply (Doc. No. 185).

Throughout this Order the Court has provided the majority of the factual background and the applicable law relevant to this dispositive motion. The Court will not

repeat that information here but will reiterate any previous statements or provide any previously unmentioned information as is necessary.

A. The '669 and '261 Patents

Based upon the Court's ruling in section V, the Court declares MOOT Plaintiff's Motion for Partial Summary Judgment on Counts I-IX of the Fourth Amended Complaint (Doc. 169) with respect to Counts I and II.

B. The '612 and '197 Patents

Based upon the Court's ruling in section VII(B), the Court invites the parties to rebrief this issue in light of the Court's construction of the terms "physical indicia", "motor", and "tracks location of said motor" in Section III(E). Plaintiff L-F's revised motion is due on November 19, 2001, Defendant Medrad's response is due on December 10, 2001, and Plaintiff L-F's reply is due on December 31, 2001. Thus, the Court **RESERVES JUDGMENT** on L-F's motion with respect to Counts III and IV.

IX. CONCLUSION

In conclusion:

- Plaintiff's Motion for Partial Summary Judgment of Claim Construction (Doc. 164) is **GRANTED** insofar as the Court has construed the claims;
- Defendant's Motion for Partial Summary Judgment of Invalidity for Lack of Enablement of the Asserted Claims of the '669 and '261 Patents (Doc. 168) is **MOOT**;

- Defendant's Motion for Partial Summary Judgment of Invalidity and Non-Infringement of the Asserted Claims of the '669 and '261 Patents (Doc. 57) is **MOOT IN PART AND GRANTED IN PART**;

- Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612 and '197 Patents Because Defendant Practices its Own Patent Which is Prior Art to the Asserted Patents (Doc. 162) is **NOT RULED ON** because the Court **RESERVES JUDGMENT** pending further briefings;

- Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. 167) is **DENIED IN PART** and **NOT RULED ON IN PART** because the Court **RESERVES JUDGMENT** pending further briefings;

- Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. 169) is **MOOT IN PART** and is **NOT RULED ON IN PART** because the Court **RESERVES JUDGMENT** pending further briefings.

IT IS SO ORDERED

Date: 10-17-01

/s/ Sandra S. Beckwith
Sandra S. Beckwith
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Liebel-Flarsheim Co.	:	
Plaintiff,	:	
vs.	:	Case C-1-98-858
Medrad Inc.,	:	
Defendant.	:	

ORDER

(Filed Feb. 19, 2002)

This matter is before the Court on multiple motions for partial summary judgment. In an Order filed October 18, 2001 ("the Oct. 18th Order"), the Court ruled on a number of these motions and reserved judgment on the remaining motions pending rebriefing by the parties. (Doc. No. 247). In this Order, the Court will address the revised motions for partial summary judgment (Doc. Nos. 248, 249, and 250/251) filed pursuant to its Oct. 18th Order.

I. GENERAL BACKGROUND

The patents at issue, United States Patent No. 5,662,612 ("the '612 patent") and United States Patent No. 5,928,197 ("the '197 patent"), are part of a series of patents that relate to medical devices known as powered injectors which deliver contrast agents from a syringe into a patient's bloodstream for certain medical diagnostic procedures. (Doc. No. 30, Exhs. 1-4). The '612 and '197 patents, filed on June 26, 1995 and August 28, 1997, respectively, involve the automatic control of the plunger drive in order

to automate its movement.[1] (Doc. No. 30, Exhs. 3 and 4). The injector disclosed in the patents includes structure and control circuitry that detect physical indicia on a syringe, which relate to various physical properties of the syringe. The control circuitry of the injector uses these various physical properties to compute the location of the plunger, which is then used by the control circuitry to determine when to halt the movement of the plunger drive.

Plaintiff Liebel-Flarsheim Co. ("L-F") initiated this lawsuit on November 13, 1998, claiming that Defendant Medrad, Inc. ("Medrad"), through its manufacture, use, marketing, and/or sale of various injectors and syringes, infringed, contributorily infringed, and/or induced infringement of a number of patents, including the '612 and '197 patents. (Doc. Nos. 1, 4, 5, 23, and 30). Numerous partial summary judgment motions have been filed in this matter. (Doc. Nos. 57, 162, 164, 167, 168, and 169). In its Oct. 18th order, the Court disposed of a number of these motions but reserved judgment, in whole or in part, on the following motions:

1. Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612 and '197 Patents Because Defendant Practices its Own

[1] The '612 and '197 patents, both titled "Controlling Plunger Drives for Fluid Injections in Animals", issued on September 2, 1997 and July 27, 1999, respectively. The '612 and '197 patents are continuations of a patent that was filed on November 27, 1993, but was subsequently abandoned. (Doc. No. 167, Exh. 4). Therefore, the '612 and '197 patents claim an effective filing date of November 27, 1993. Furthermore, as continuation applications, the '612 and '197 patents have the same specifications and drawings.

Patent Which is Prior Art to the Asserted Patents (Doc. No. 162),

2. Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. No. 167), and

3. Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. No. 169).

Per the Court's Oct. 18th Order, the parties have filed the following motions:

1. Defendant Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art (Doc. No. 249),

2. Defendant Medrad Inc.'s Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. Nos. 250/251), and

3. Plaintiff Liebel-Flarsheim's Resubmitted Motion for Partial Summary Judgment of Infringement on United States Patent Nos. 5,662,612 and 5,928,197 (Doc. No. 248).

The parties have filed the appropriate memoranda in opposition (Doc. Nos. 256, 257, and 255) and reply briefs

(Doc. Nos. 259, 258, and 262).[2] The Court is now prepared to rule on these motions.[3]

II. DISCUSSION

As a result of the Court's ruling in its Oct. 18th Order, the single remaining issue before the Court is whether the injectors and syringes manufactured and sold by Medrad infringe certain claims of the '612 and '197 patent. In its Oct. 18th Order, the Court discussed in great detail the applicable law relevant to summary judgment, patent claim construction, patent infringement, and patent validity. (Doc. No. 247, pp. 6-14, 5-52, 62-64, and 67-71). The Court will not repeat that discussion here but incorporates it by reference into this Order. Of course, the Court will reiterate any previous statements or provide any previously unmentioned information as is necessary.

Because L-F's motion for summary judgment of infringement (Doc. No. 248) and Medrad's motion for summary judgment of non-infringement and invalidity (Doc. Nos. 250/251) overlap on numerous technical issues, the Court will analyze those motions together.

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[2] The Court has also considered all sur-replies and responsive pleadings filed by the parties. (Doc. Nos. 263, 266, 268, and 270).

[3] Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612 and '197 Patents Because Defendant Practices its Own Patent Which is Prior Art to the Asserted Patents (Doc. No. 162); Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. No. 167), and Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. No. 169) are superseded by the parties' revised motions (Doc. Nos. 259, 258, and 262) and are, therefore, DENIED, on that basis.

A. Infringement of the '612 and '197 Patents

The '612 and '197 patents disclose an injector which automatically controls the advancement and retraction of the plunger drive, freeing the operator of the injector to complete other tasks. (Doc. No. 30; Exh. 3, Col. 3, lines 7-8; and Exh. 4, Col. 3, lines 6-7). L-F claims that Medrad's Envision™ and Vistron® injectors and the syringes compatible with those injectors ("the Accused Injectors" and "the Accused Syringes") infringe certain claims of the '612 and '197 patents. (Doc. No. 30, ¶¶ 21-29 and 72-79). Specifically, L-F alleges that the Accused Injectors and Syringes infringe claims 7, 8, 10, and 11 of the '612[4] patent

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[4] For purposes of the Court's infringement analysis, the relevant claims of the '612 patent are independent claims 7 and 10.

Claim 7 and 10 of the '612 patent state:

7. An injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at a distal end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to a syringe installed on said injector for detecting a physical indicia on said syringe related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the location of a plunger within said syringe relative to an end of said syringe, by relating said electrical signal to the tracked location of said motor.

10. A method of controlling an injector of the type having a motor which advances and retracts a plunger located within a syringe toward and away from a nozzle located at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

(Continued on following page)

and claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22, 23, 25, and 27 of the '197 patent ("the asserted claim").[5] (Doc. No. 248, p. 1; Doc. No. 30, Exh. 3 and 4).

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detecting a physical indicia on said syringe installed on said injector, said indicia being related to the capacity of said syringe, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the location of a plunger within said syringe relative to an end of said syringe by relating said electrical signal to the tracked location of said motor.

(Doc. No. 30, Exh. 3).

[5] For purposes of the Court's infringement analysis, the relevant claims of the '197 patent are independent claims 1, 4, 7, 10, 13, 16, 19, 22, 25, and 27.

Claim 1 and 4 of the '197 patent state:

1. An injector and syringe, comprising:

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector,

a motor in the injector which advances and retracts the plunger located within the syringe toward and away from the nozzle of the syringe to inject fluid into or out of an animal subject, and

a controller in the injector adapted for use with syringe assemblies which have differing capacities, comprising:

a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and

a control circuit which causes said motor to move and tracks the location of said motor while moving said motor, wherein said control circuit computes the relative location of said plunger within said syringe, using said electrical signal and the tracked location of said motor.

(Continued on following page)

4. A method of controlling an injector of the type having a motor which advances and retracts the plunger located within the syringe toward and away from a nozzle at an end of the syringe to inject fluid into or out of an animal subject, adapted for use with syringe assemblies which have differing capacities, comprising:

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the distance of the plunger from an end of said syringe when said syringe is initially installed on said injector, and generating an electrical signal representative of said physical indicia,

causing said motor to move,

tracking the location of said motor while moving said motor, and

computing the relative location of said plunger within said syringe, using said electrical signal and the tracked location of said motor.

(Doc. No. 30, Exh. 4).

Claims 7, 10, 13, 16, 19, and 22 are the same as claims 1 and 4 in all relevant respects except that the physical indicia in those claims relate to the amount of fluid in the syringe, the end of travel position of an injector ram, and the range of travel of an injector ram.

Claim 25 and 27 of the '197 patent state:

25. An injector and syringe, comprising:

a syringe having a plunger, a nozzle located in the front of said syringe, and physical indicia,

a motor which advances and retracts the plunger within the syringe toward and away from the nozzle to inject fluid into or out of an animal subject, and

a controller comprising:

a control circuit which causes the motor to move and tracks the location of the motor while moving the motor, and

a memory storing an offset value which is related to the capacity of said syringe,

wherein the control circuit is operable obtain an offset value from physical indicia detected on the syringe, and the control circuit computes a value indicative of the location of said plunger within said syringe by applying the stored offset value to the tracked location of said motor, and ceases

(Continued on following page)

The asserted independent claims describe an injector comprised of a syringe, a motor, a detector, and a control circuit. (Doc. No. 30, Exh. 3 and 4). The syringe disclosed in the claims includes physical indicia related to various physical properties of the syringe. (*Id.*) During operation of the injector, the detector described in the claims detects the physical indicia on the syringe and generates an electrical signal representative of such physical indicia. (*Id.*) The control circuit then uses this electrical signal and other information to determine the location of the plunger drive. (*Id.*) The location of the plunger drive is then used by the control circuit to determine when to halt the movement of the plunger drive. (*Id.*) Several of the asserted claims also describe the method of operating such an injector. (*Id.*).

Medrad argues that the Accused Injectors and Syringes do not infringe the asserted claims because the

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motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

27. A method of controlling an injector of the type having a motor which advances and retracts a plunger within a syringe toward and away from a nozzle located in the front of the syringe to inject fluid into or out of an animal subject, comprising:

causing the motor to move and tracking the location of the motor while moving the motor,

detecting a physical indicia on a syringe installed on said injector, said indicia being related to the capacity of said syringe, to obtain an offset value,

computing a value indicative of the location of said plunger within said syringe by applying the stored offset value to the tracked location of said motor, and

ceasing motion of said plunger when said computed value indicates that said plunger is at an end of said syringe.

(Doc. No. 30, Exh. 4).

Accused Injectors and Syringes are missing a number of elements disclosed in the claims. (Doc. Nos. 250/251, p.1). In particular, Medrad argues that the Accused Injectors and Syringes are missing the following claim elements:

- a motor which advances and retracts a plunger;
- adapted for use with syringe assemblies;
- a detector located proximate to a syringe;
- a detector located proximate to the syringe;
- detecting a physical indicia on a syringe;
- physical indicia on said syringe relating to the capacity of the syringe, the distance of the plunger from the end of the syringe, the amount of fluid in the syringe, the end of travel position of an injector ram, the range of travel of an injector ram, or an offset value;
- relating said electrical signal to the tracked location of said motor;
- using said electrical signal and the tracked location of said motor; and
- an electrical signal representative of said physical indicia.

(Doc. Nos. 250/251, pp. 3-4). Medrad argues that because the Accused Injectors and Syringes are missing these elements, they cannot infringe the '612 and '197 patents as a matter of law, and Medrad is, therefore, entitled to summary judgment of non-infringement of the '612 and '197 patents. (Doc. Nos. 250/251, pp. 4, 27-28).

Before addressing the parties' arguments in more detail, it is worth noting that L-F is only claiming the Accused Injectors and Syringes literally infringe the asserted claims of the '612 and '197 patent. (Doc. No. 248, pp. 15-16, and 20). L-F has not argued infringement under the doctrine of equivalents nor responded to Medrad's argument of non-infringement under this doctrine.[6] Literal infringement occurs when the accused product is precisely described in a patent claim. *SRI Int'l v. Matsushita Electric Corp.*, 775 F.2d 1107, 1123 (Fed.Cir. 1985). It is well recognized that if any claim limitation is absent from the accused device, there can be no literal infringement as a matter of law. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed.Cir. 1999), *cert. denied*, 529 U.S. 1066 (2000) (quoting *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed.Cir. 1998)). Thus, if even one of the elements of the asserted claims is missing from the Accused Injectors and/or Syringes, they cannot infringe the '612 and '197 patents as a matter of law.

With this principle in mind, the Court finds that it need not address each and every claim element identified as missing by Medrad because it finds that the Accused Syringes are missing at least one critical element of the

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[6] In its summary judgment motion of non-infringement, Medrad notes that it is unclear whether L-F is alleging infringement of the '612 and '197 patents under the doctrine of equivalents and argues that even if L-F is making such an allegation, the Accused Injectors and Syringes do not infringe the patents under the doctrine. (Doc. Nos. 250/251, p. 9, fn. 4). In its memorandum in opposition, L-F does not respond to or even acknowledge Medrad's non-infringement under the doctrine of equivalents argument. (Doc. No. 257). Furthermore, in its own summary judgment motion of infringement, L-F only alleges that the Accused Injectors and Syringes literally infringe the '612 and '197 patents (Doc. No. 248, p. 20).

asserted claims – physical indicia relating to the capacity of the syringe, the distance of the plunger from the end of the syringe, the amount of fluid in the syringe, the end of travel position of an injector ram, or the range of travel of an injector ram or physical indicia that provides an offset value[7]. Because the Accused Syringes are missing this claim element, it follows that the Accused Injectors are missing any claim elements that rely on the existence of such physical indicia.

Before proceeding further in its analysis, the Court believes it would be helpful to describe the relevant aspects of the operation of the Accused Injectors and Syringes, a factual issue that does not appear to be in dispute by the parties. The Accused Injectors are compatible with three types of syringes, a 200 ml empty syringe, a 125 ml empty syringe, and a Bracco prefilled syringe[8,9].

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[7] In its Oct. 18th Order, the Court construed the term "physical indicia" as a tangible mark on a syringe relating to various properties of the syringe such as capacity of a syringe, the distance of the plunger from the end of a syringe, the amount of fluid in a syringe, the end of travel position of an injector ram, the range of travel of an injector ram, or an offset value. (Doc. No. 247, p. 45). It has become clear to the Court during its analysis for this Order that Claim 25 of the '197 patent does not describe physical indicia in terms of "relating to" an offset value. (Doc. No. 30, Exh. 4). Rather, according to Claim 25, the information detected from the physical indicia actually constitutes the offset value, "a control circuit obtain[s] an offset value from physical indicia detected on the syringe". (Doc. No. 30, Exh. 4; Doc. No. 248, Exh. 16, Helmicki Aff., ¶ 7(f)). Thus, the Court must clarify its construction of the term "physical indicia" with respect to an offset value as "a tangible mark that provides an offset value".

[8] Bracco pre-filled syringes are available in 75 ml, 100 ml and 150 ml sizes. (Doc. Nos. 250/251, Exh. 5, ¶ 8).

[9] The Vistron injector can also sense an adapter that allows for a fourth type of syringe. (Doc. Nos. 250/251, Exh. 5, Braunstein Decl., ¶ 10).

(Doc. Nos. 250/251, Exh. 5, Braunstein Decl., ¶ 8). Each of these syringes has flanges to the rear of the syringe. *(Id.* at ¶6). Depending on the type of syringe, the flanges have indents at various locations or have no indents at all. *(Id.* at ¶6). When the syringe is installed on the injector, these indent(s)/lack of indents interact with a series of pins attached to the injector. (*Id.*). A pin is depressed or released depending on the presence or absence of an indent. (*Id.*). Based on the position of these pins, sensors send electrical signals, representing a value of either a 1 or 0, to the injector head microprocessor which interprets these signals to determine the type of syringe installed. *(Id.* at ¶6-7). Depending on the syringe type, the injector head microprocessor generates a binary reference number of 1, 2, or 4, for the 125 ml empty syringe, the 200 ml empty syringe, and the Bracco prefilled syringe, respectively.[10]

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[10] In his affidavit, L-F's expert, Arthur Helmicki, states that "[t]he Medrad Brief . . . states that the injector microprocessor only receives a value of 1, 2 or 4 from the optical sensors reading the detents . . . ". (Doc. No. 257, Exhibit 8, Post-Claim Construction Affidavit of Arthur J. Helmicki, ¶ 12). The description in Medrad's brief, which is based on the declaration of Thomas Braunstein, Manager of Advanced Manufacturing Engineering for Medrad, clearly states that the injector microprocessor generates the values of 1, 2, or 4 from the electrical signals sent by the sensors. (Doc. No. 251, p. 6). In his declaration, Braunstein explains that the injector microprocessor receives an electrical signal of 0 or 1 for each pin depending on the position of the pin. (Doc. Nos. 250/251, Exh.5, Braunstein Decl., ¶ 6). Based on the configuration of these values, the microprocessor determines the type of syringe installed and then generates a value of 1, 2, or 4 as a reference number. *(Id.* at ¶7). Thus, the injector microprocessor does not ***receive*** values of 1, 2, or 4 but ***generates*** these values based on information received from the sensors.

Although Helmicki misstates Medrad's description of the operation of the injector, it appears from the following description in his affidavit that he correctly understands the operation of the injectors:

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(*Id.* at ¶7). The head microprocessor communicates the appropriate reference number to the system microprocessor, which then uses the reference number as an index to look up various syringe parameters in a table. (Doc. Nos. 250/251, p. 6).

Medrad argues that because the only information gleaned from the indents is the "type" of syringe, the Accused Syringes do not have physical indicia as described in the asserted claims.[11] (Doc. Nos. 250/251, p. 16-18). The

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> The determination of the syringe configuration [type][1] is made by the software source code used in the Envision and Vistron CT injectors based upon the electrical signals generated by the switches on the injector.
>
> (Doc. No. 248, Exh. 16, Helmicki Aff., ¶ 10).
>
> [1]Medrad assumes that the term configuration, as used by Helmicki, has the same meaning as the term type. (Doc. No. 255, p. 7, fn. 4). L-F does not dispute this assumption.

For purposes of the Court's analysis, whether the injector microprocessor receives the values of 1, 2, or 4 from the sensors or generates these values based on electrical signals from the sensors is not critical.

[11] The Court has construed physical indicia as a "tangible mark" relating to various syringe properties. The parties do not dispute that the Bracco prefilled syringes and the 100 ml non-Medrad syringes used with the Vistron injector adapter do not have any indents on the syringe flanges. Despite L-F's argument to the contrary, no reasonable jury could conclude that a complete absence of indents constitutes a "tangible mark." (Doc. No. 257, p. 14-15). *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986). Therefore, the Bracco prefilled syringes and the 100 ml non-Medrad syringes are missing "physical indicia" as that term is used in the asserted claims.

Medrad also argues that the term "physical indicia" is plural and because the Accused Syringes that have indents only have one indent sensed during the operation of the injector, these syringes do not have physical indicia as contemplated by the asserted claims. (Doc. Nos. 250/251, pp. 14-15). This issue is not relevant to the Court's analysis and will, therefore, not be resolved at this time. Furthermore, the

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asserted claims disclose physical indicia related to various syringe properties such as capacity of the syringe, distance of the plunger from the end of the syringe, amount of fluid in the syringe, end of travel position of an injector ram, or range of travel of an injector ram or physical indicia that provide an offset value. As Medrad correctly points out, these properties clearly do not include the "type" of syringe installed on the injector. (Doc. Nos. 250/251, pp. 2 and 16). Thus, according to Medrad, the Accused Syringes are missing the "physical indicia" claim element.

L-F counters that because Accused Injectors use the "type" of syringe to ultimately determine the various syringe properties described in the claims (by looking up the information in a table and using that information to determine syringe properties), the indents are physical indicia related to various syringe properties as disclosed in the asserted claims. (Doc. No. 257, p. 22; Doc. No. 262, p. 8).

The difference in the parties' infringement analyses comes down to an issue of claim construction. Medrad's analysis rests on its construction of the term "related to"

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parties should not assume the Court is using the term "physical indicia" in either a plural or singular form in this Order.

Additionally, Medrad contends that the term "physical indicia" requires that information be "encoded" on the syringe. (*See* Doc. Nos. 250/251, pp. 23-24). Medrad argues that the indents on the Accused Syringes do not have any information encoded in them. (Doc. Nos. 250/251, pp. 23-24). Therefore, according to Medrad, the Accused Syringes do not have physical indicia as required by the claims. (Doc. Nos. 250/251, pp. 23-24). This issue is not relevant to the Court's analysis and will, therefore, not be resolved at this time.

as describing a direct one-to-one relationship.[12] According to Medrad, the asserted claims require that the information detected from the physical indicia must actually be the capacity of the syringe, the distance of the plunger from the end of the syringe, the amount of fluid in the syringe, the end of travel position of an injector ram, the range of travel of an injector ram, or an offset value. (Doc. Nos. 250/251, p. 19). L-F, on the other had, views the term "related to" as encompassing direct and indirect relationships. As such, L-F argues that the physical indica are "related to" various syringe properties if the information detected from physical indicia is the actual syringe properties or is merely used in some manner to determine syringe properties, as in the case of the Accused Injectors which use the information detected from the physical indicia as an index to look up syringe parameters in a table and then use those parameters to determine various syringe properties. (Doc. No. 257, p. 22; Doc. No. 262, p. 8).

Questions of claim construction are questions of law to be decided by the court. *Wang Labs., Inc. v. America Online, Inc.,* 197 F.3d 1377, 1380-81 (Fed.Cir. 1999). When construing a claim term, the court must first rely on the intrinsic evidence, *i.e.*, the claims, the specification, and the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1582 (Fed.Cir. 1996); *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 979 (Fed.Cir. 1995), *aff'd,* 517 U. S. 370 (1996)). Extrinsic evidence should not be considered unless the intrinsic evidence does

[12] The Court did not construe the term "related to" in its Oct. 18th Order. The Court used the term in its definition of the term "physical indicia" but took no position on the meaning of the term "related to" as it is used in the asserted claims.

not resolve an ambiguity in a challenged claim. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed.Cir. 1999).

In the present case, the meaning of the term "related to" is readily apparent from the language of the asserted claims themselves. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed.Cir. 2001) (In claim construction, the court first considers the language of the claim.). The language of the asserted independent claims, except Claim 27 of the '197 patent, is virtually identical except that each claim refers to a different syringe property. For purposes of the Court's analysis, it will use the claim language of Claim 7 of the '197 patent as an example and will note any differences in the other claims' language as appropriate.[13]

The pertinent claim language of Claim 7 of the '197 patent states as follows:

> An injector and syringe, comprising:
>
> a syringe having . . . physical indicia related to the amount of fluid in the syringe . . . , and . . .
>
> a controller in the injector . . . comprising:
>
> a detector . . . for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia, and a control circuit . . . wherein said control computes

[13] Independent Claims 7 of the '612 and 1, 7, 13, 19, and 25 of the '197 patent describe the injector claimed in the patents. (Doc. No. 30, Exhs. 3 and 4). Independent Claims 10 of the '612 patent and 4, 10, 16, 22, and 27 of the '197 patent describes methods of using an injector which correspond to the claims describing the injector. (*Id.*).

> the amount of fluid in said syringe, using said electrical signal and the tracked location of said motor.

From this language, one can conclude that the after detecting the physical indicia on the syringe, a detector located in the injector generates an electrical signal that represents the information detected from the physical indicia:

> a detector . . . for detecting the physical indicia on said syringe, and ***generating an electrical signal representative of said physical indicia,*** and

The control circuit of the injector then uses this electrical signal and the tracked location of the motor to compute various syringe properties:

> control circuit ***computes***[14] ***the amount of fluid*** in said syringe, ***using <u>said</u> electrical signal***[15] and the tracked location of said motor.[16]

Of key importance to the Court's analysis is that the electrical signal referenced in the asserted claims is

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[14] Claim 13 of the '197 patent uses the term "determines" rather than "computes". The parties have not argued nor does it appear that this difference in language has any significance.

[15] Claim 7 of the '612 patent uses the term "by relating said electrical signal" rather than "using said electrical signal". The parties have not argued nor does it appear that this difference in language has any significance.

[16] Claim 19 of the '197 patent computes the "range of travel of said ram" using the electrical signal without reference to the tracked location of the motor.

generated by the detector and not the control circuit.[17] It is the signal generated by the detector that is used in the computation of various syringe properties. The claim language does not describe using the electrical signal generated by the detector to ascertain information from another source and then using this ascertained information to compute syringe properties. Thus, the information from the physical indicia that is represented by the electrical signal generated by the detector must be of the type that can be directly used in the computation of various syringe properties without reference to some outside source of information.[18] Under the plain language of the

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[17] L-F's expert, Helmicki, states the following in his affidavit:

> [Medrad's] assertion is based upon the erroneous assumption that the "electrical signal" referenced in the claims is, and can only be, the signal output by the optical sensors (slotted detectors) themselves, excluding the multiple electrical signals derived from the output of the optical sensors, which also represent the syringe information encoded in the indicia.
>
> (Doc. No. 257, Exh. 8, Helmicki Post-Claim Construction Aff., ¶ 10).

This excerpt demonstrates that L-F's argument is based on the assumption that the electrical signal disclosed in the claims does not necessarily have to be the same electrical signal generated by the detector. L-F's (and Helmicki's) assumption is incorrect. The ***only*** electrical signal described in the claims is the original electrical signal generated by the detector.

[18] Claims 25 and 27 do not track the language of the other asserted claims. As already discussed in footnote 7, the physical indicia described in Claim 25 constitutes an actual offset value rather than just relating to an offset value. Claim 27, which describes the method of controlling an injector, states in pertinent part that:

> A method of controlling an injector . . . comprising:
>
> detecting a physical indicia on a syringe installed on said injector, said indicia being related to the capacity of said syringe, to obtain an offset value, . . .
>
> (Doc. No. 30, Exh. 4).

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asserted claims, therefore, physical indicia is/are "related to" various syringe properties when the information detected from the physical indicia is/are the actual syringe properties or can be directly used in the computation of the various syringe properties without reference to some other source of information.

Thus, the Court adopts neither parties' proposed construction of the term "related to" as it is used in the asserted claims.[19] Rather, the Court finds that the term "related to" encompasses both a direct and indirect relationship, with the indirect relationship being limited to information that can be directly used in the computation

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At first glance, it would appear that the term "obtain", as it used in Claim 27, is not the same as the term "compute" and could, arguably, encompass references to an outside source of information. However, the term "obtain" must be read in light of the specification of the '197 patent, which states that "the offset value may be automatically computed by detecting physical indica on the syringe or extender which indicates the length of the syringe." (Doc. No. 30, Exh. 4, Col. 3, line 1 – Col. 4, line 1-2). Thus, the specification equates the term "obtain" with the term "compute".

[19] L-F argues that its construction of the term "related to" is supported by the deposition testimony of Thomas Braunstein, Medrad's 30(b)(6) witness. L-F is incorrect. First, Braunstein's deposition testimony is irrelevant to the Court's claim construction analysis because the Court can construe the term "related to" based solely on the intrinsic evidence. Therefore, the Court should not rely on any extrinsic evidence, such as Braunstein's deposition testimony. Second, Braunstein's deposition testimony regarding the relationship of the indents on the Accused Syringes to various syringe properties is of little assistance to the Court because Braunstein was not testifying about such relationships in terms of the Court's construction of the term "relate to" as it is used in the asserted claims. Consequently, Braunstein's deposition testimony does not support L-F's proposed claim construction. Furthermore, despite L-F's argument to the contrary, there is nothing inconsistent between Braunstein's deposition testimony and his Second Post-Claim Construction Declaration. (Doc. No. 262, pp. 6-7).

of the various syringe properties without reference to some other source of information.

Having construed the meaning of the claims, the Court must now apply the asserted claims to the Accused Injectors and Syringes, which is a question of fact. *Wang Labs.*, 197 F.3d at 1380-81. As such, summary judgment is only appropriate if the Court finds that, when viewing the evidence in the light most favorable to L-F, no reasonable jury could conclude the Accused Injectors and Syringes infringe the '612 and '197 patents. *See Anderson*, 477 U.S. at 250.

As already explained, the information generated by the sensors from the indent(s)/lack of indents on the Accused Syringes are the values of 1 or 0 for each sensor, which are used by the microprocessor to generate reference numbers of 1, 2, or 4. None of these values or reference numbers[20], standing alone, can be used to compute the various syringe properties disclosed in the asserted claims. It is only by referencing some other source of information, a table, that the injector can ascertain the information necessary to determine various syringe properties. Thus, the information gleaned from the indent(s)/lack of indents is not the type of information that can be used to compute syringe properties without referencing some other source of information. Consequently,

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[20] Because of the confusion created by Helmicki's affidavit and mindful that it should consider the evidence in the light most favorable to L-F, the Court is considering the reference numbers generated by the microprocessor in its infringement analysis. In reality, however, the electrical, signals representing the values of 1 or 0 generated by the sensors are the only electrical signals that should actually be considered. *See supra* fn. 10.

the information detected from the indent(s)/lack of indents is not "related to" various syringe properties as that term is used in the asserted claims. Thus, any reasonable jury would find that the Accused Syringes are missing the "physical indicia" claim element because any information detected from the physical indicia[21] does not "relate to" the various syringe properties as required by the asserted claims. Furthermore, it follows that any reasonable jury would find that the Accused Injectors are missing any claim elements that rely on the existence of such physical indicia.

Because the Accused Injectors and Syringes are completely missing an essential element of the claims and do not appear to have a substantial equivalent of that element, they do not infringe the '612 and '197 patents, either literally or under the doctrine of equivalents, and Medrad is, therefore, entitled to summary judgment of non-infringement. *Elkay Mfg. Co.*, 192 F.3d at 980 (No literal infringement if claim limitation is missing.); *Vehicular Technologies Corp. v. Titan Wheel International, Inc.*, 141 F.3d 1084, 1089 (Fed. Cir. 1998) (No infringement under the doctrine of equivalents if substantial equivalent of a claim limitation is missing).

Because the Court can resolve the question of infringement of the '612 and '197 patents on the forgoing issue, it need not, at this time, resolve the other numerous and varied issues raised by the parties. To avoid any confusion in any further proceeding on this matter, the

[21] The Court is assuming the indents on the Accused Syringes constitute a "tangible mark" for purposes of this analysis only. The Court is not resolving this issue at this time.

Court wishes to make it clear that it is not resolving any of the following issues in this or any other order issued to date in this case:

- whether the indents on the Accused Syringes constitute a tangible mark;
- whether physical indicia, as used in the claims, is plural or singular;
- whether L-F admitted during prosecution of the '612 patent that the apparatus and method used by the Accused Injectors to determine the type of syringe in place in the injector is not covered by the asserted claims;
- whether the Accused Injectors use an electrical signal representative of said physical indicia while moving the motor[22];
- whether the Accused Injectors are adapted for use with syringe assemblies;
- whether the indents on the Accused Syringes encode information;
- whether Medrad's injectors have a detector located proximate to the syringe when installed on said injector for detecting the physical indicia on said syringe, and generating an electrical signal representative of said physical indicia;

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[22] To eliminate any confusion created by its Oct. 18th, the Court construes the term "motor" as a stationary mechanism that rotates causing the movement of the gears in the gearbox and the term "tracking the location of the motor" as the monitoring of the rotation of the motor.

- whether Medrad's injectors have a motor which advances and retracts the plunger; and
- whether Medrad's injectors and syringes have an offset value.

Thus, the Court **GRANTS**, with respect to non-infringement, Defendant Medrad Inc.'s Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. Nos. 250/251), and declares the motion **MOOT** with respect to invalidity. The Court **DENIES** Plaintiff Liebel-Flarsheim's Resubmitted Motion for Partial Summary Judgment of Infringement on United States Patent Nos. 5,662,612 and 5,928,197 (Doc. No. 248).

B. Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art

Based upon the Court's ruling in Section A regarding non-infringement, the Court declares **MOOT** Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art (Doc. No. 249).

C. Motions to Strike

In conjunction with its revised briefings, L-F filed a Motion to Strike the Post-Claim Construction Declaration of Joseph B. Havrilla (Doc. No. 253) and a Motion to Strike Portions of Medrad's Memorandum in Support of its Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the

'612 and '197 Patents and to Strike In Its Entirety Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents because Medrad Practices the Prior Art (Doc. No. 254). Based upon the Court's ruling in Section A regarding non-infringement, the Court declares these motions to strike **MOOT.**

III. CONCLUSION

In conclusion:

- Defendants Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art (Doc. No. 249) is **MOOT,**
- Defendant Medrad Inc.'s Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. Nos. 250/251) is **GRANTED IN PART** and declared **MOOT IN PART**, and
- Plaintiff Liebel-Flarsheim's Resubmitted Motion for Partial Summary Judgment of Infringement on United States Patent Nos. 5,662,612 and 5,928,197 (Doc. No. 248) is **DENIED**;
- Defendant's Motion for Partial Summary Judgment of Non-Infringement of the '612 and '197 Patents Because Defendant Practices its Own Patent Which is Prior Art to the Asserted Patents (Doc. No. 162) is **DENIED,**

- Defendant's Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents (Doc. No. 167) is **DENIED**,

- Plaintiff's Motion for Partial Summary Judgment of Infringement on Counts I-IX of the Fourth Amended Complaint (Doc. No. 169) is **DENIED**,

- Plaintiff Liebel-Flarsheim's Motion to Strike the Post-Claim Construction Declaration of Joseph B. Havrilla (Doc. No. 253) is **MOOT**;

- Plaintiff Liebel-Flarsheim's Motion to Strike Portions of Medrad's Memorandum in Support of its Renewed Motion for Partial Summary Judgment of Non-Infringement and Invalidity of the Asserted Claims of the '612 and '197 Patents and to Strike In Its Entirety Medrad's Revised Motion for Partial Summary Judgment of Non-Infringement of the Asserted Claims of the '612 and '197 Patents Because Medrad Practices the Prior Art (Doc. No. 254) is **MOOT**; and

- Defendant Medrad's Motion for Leave to File a Sur-Reply to Plaintiff Liebel-Flarsheim Company's Reply Memorandum in Support of its Resubmitted Motion for Partial Summary Judgment of Infringement of United States Patent Nos. 5,662,612 and 5,928,197 (Doc. No. 263) is **GRANTED**;

- Defendant Medrad's Motion for Leave to File a Sur-Reply to Plaintiff Liebel-Flarsheim Company's Reply Memorandum in Support of its Motion to Strike Pursuant to Fed. R. civ. P. 37(C) (Doc. No. 267) is **GRANTED**; and

- Plaintiff Liebel-Flarsheim Company's Motion for Leave to File Sur-Reply to Medrad's Motion for Leave to File a Sur-Reply to Plaintiff Liebel-Flarsheim Company's Reply Memorandum (Doc. No. 270) is **GRANTED**.

IT IS SO ORDERED

Date 2-15-02 /s/ Sandra S. Beckwith
Sandra S. Beckwith
United States District
Judge

United States Court of Appeals
for the Federal Circuit

03-1082, -1165

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT INC.,

Plaintiffs-Appellants,

v.

MEDRAD, INC.,

Defendant-Cross Appellant.

ORDER

(Filed Apr. 2, 2004)

A combined petition for panel rehearing and for rehearing en banc having been filed by the CROSS-APPELLANT, and a response thereto having been invited by the court and filed by the APPELLANTS, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on April 9, 2004.

FOR THE COURT,

/s/ Jan Horbaly (AV)
Jan Horbaly
Clerk

Dated: April 2, 2004

cc: J. Robert Chambers
Frederick H. Colen

LIEBEL-FLARSHEIM CO V MEDRAD INC, 03-1082, -1165
(DCT – 98-CV-858)

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* Note: Pursuant to Fed. Cir. R. 47.6, this order is not *
* citable as precedent. It is a public record. *
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